Aclaris Therapeutics, Inc.
Form 10-K
March 15, 2017
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF

THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2016 Commission file number 001-37581

ACLARIS THERAPEUTICS, INC.

Incorporated under the Laws of the State of Delaware	I.R.S. Employer Identification No. 46-0571712

101 Lindenwood Drive, Suite 400

Malvern, PA 19355

(484) 324-7933

Securities registered pursuant to Section 12(b) of the Exchange Act:

Title of Each Class:	Name of Each Exchange on which Registered
Common Stock, $0.00001 par value	The NASDAQ Stock Market, LLC

Securities registered pursuant to Section 12(g) of the Exchange Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulations S-K (§ 229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
Yes No

As of June 30, 2016, the last business day of the registrant's last completed second quarter, the aggregate market value of the registrant's common stock held by non-affiliates of the registrant was approximately $156.5 million based on the closing price of the registrant's common stock, as reported by the NASDAQ Global Select Market, on such date.

As of March 14, 2017, 26,088,866 shares of common stock, $0.00001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Company's definitive proxy statement, to be filed pursuant to Regulation 14A under the Securities Exchange Act of 1934, for its 2016 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part I, Item 1. "Business," Part I, Item 1A. "Risk Factors," and Part II, Item 7. "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. 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," "project," "potential," "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 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 Annual Report, we caution you that these statements are based on a combination of facts and 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 our drug candidates;
- the timing of our Marketing Authorization Application, or MAA, filing for A-101 40% Topical Solution for the treatment of seborrheic keratosis, or SK, and the timing of our investigational new drug application, or IND, for ATI-50002;
- 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 40% Topical Solution 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 "Item 1A. Risk Factors" in this Annual Report 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 Annual Report 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. The forward-looking statements in this Annual Report represent our views as of the date of this Annual Report. We anticipate that subsequent events and developments may cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, 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, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

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PART I

Item 1. Business

Overview

We are a clinical-stage biotechnology company focused on identifying, developing and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. Our lead drug candidate, A-101 40% Topical Solution, is a proprietary formulation of 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. In the first quarter of 2016, we initiated two multi-center, randomized, double blinded, vehicle-controlled Phase 3 clinical trials and one open-label Phase 3 clinical trial of A-101 40% Topical Solution in patients with SK. In November 2016, we announced positive top-line results from the two pivotal Phase 3 clinical trials, which are summarized below. Based on these results, we submitted a New Drug Application, or NDA, for A-101 40% Topical Solution for the treatment of SK to the U.S. Food and Drug Administration, or FDA, in February 2017, and we intend to submit a Marketing Authorization Application, or MAA, in the European Union in the second half of 2017. We are also developing A-101 45% Topical Solution as a prescription treatment for common warts, also known as verruca vulgaris. Additionally, in 2015, we in-licensed exclusive, worldwide rights to certain inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions, including alopecia areata, or AA, vitiligo and androgenetic alopecia, or AGA. In 2016, we acquired additional intellectual property rights for the development and commercialization of certain JAK inhibitors for specified dermatological conditions. We intend to continue to in-license or acquire additional drug candidates and technologies 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 November 2016, we completed two pivotal Phase 3 clinical trials of A-101 40% Topical Solution in a combined 937 patients who each had a total of four target SK lesions located on the face, trunk and extremities. Each trial met

all primary and secondary endpoints for that trial, achieving clinically and statistically significant clearance of SK lesions. Additionally, we completed an open-label safety trial of A-101 40% Topical Solution in November 2016, in which we enrolled 147 patients. Across all three clinical trials, there were no treatment-related serious adverse events among patients treated with A-101 40% Topical Solution, and the most common adverse events reported were nasopharyngitis and sinusitis which were determined to be unrelated to A-101 40% Topical Solution. Based on these results, we submitted an NDA for A-101 40% Topical Solution for the treatment of SK to the FDA, in February 2017, and we intend to submit an MAA in the European Union in the second half of 2017. If approved, A-101 40% Topical Solution would become the first FDA-approved drug for the treatment of SK.

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We are also developing A-101 45% Topical Solution for the treatment of common warts. Although common warts are generally not harmful and in most cases eventually clear without 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 completed a Phase 2 clinical trial in August 2016 evaluating 40% and 45% concentrations of A-101 for the treatment of common warts. In this Phase 2 clinical trial, in which 90 patients completed an eight-week treatment period, we observed statistically significant improvements in the mean change in the Physician's Wart Assessment, or PWA, score and in complete clearance of common warts in patients treated with the 45% concentration of A-101 compared to placebo. In mid-2017, we plan to commence two additional Phase 2 clinical trials of A-101 45% Topical Solution to assess the dose frequency as a treatment for common warts in adult and pediatric populations.

In addition, we are developing the JAK inhibitors, ATI-50001 and ATI-50002, which we in-licensed from Rigel Pharmaceuticals, Inc., or Rigel, as potential treatments for AA. AA is an autoimmune dermatologic condition typically characterized by patchy non-scarring hair loss on the scalp and body. More severe forms of AA include total scalp hair loss, known as alopecia totalis, and total hair loss on the scalp and body, known as alopecia universalis. AA affects up to 2.0% of people globally at some point during their lifetime (i.e. incidence) and up to 0.2% of people are affected at any given time (i.e. prevalence) - with two-thirds of affected individuals being 30 years old or younger at the time of disease onset. Treatment options for the less severe, patchy forms of AA include corticosteroids, either topically applied or injected directly into the scalp where the bare patches are located, or the induction of an allergic reaction at the site of hair loss using a topical contact sensitizing agent, an approach known as topical immunotherapy. The same treatment options are utilized for the more severe forms of AA, although utilization of these treatment options for the more severe forms of AA is limited due to limited efficacy, certain side effects, and their impracticality for extensive surface areas. We are developing ATI-50001 as an oral treatment for alopecia totalis and alopecia universalis and ATI-50002 as a topical treatment for patchy AA. We submitted an IND to the FDA for ATI-50001 in October 2016 and we completed a Phase 1 clinical trial to evaluate the pharmacokinetic and pharmacodynamic properties of this drug candidate in the first quarter of 2017. We plan to initiate a Phase 2 clinical trial for ATI-50001, for the treatment of alopecia totalis and alopecia universalis, in the second half of 2017. We plan to submit an IND to the FDA for ATI-50002 in mid-2017, and to commence a Phase 2 clinical trial for this drug candidate in the second half of 2017. We also plan to develop ATI-50001 and ATI-50002 as potential treatments for vitiligo, a disorder in which white patches of skin appear on different parts of the body.

Our intellectual property portfolio contains issued patents directed to methods of use for high-concentration hydrogen peroxide compositions of at least 23% or more, including A-101 40% and 45% Topical Solutions and issued patents directed to our JAK inhibitor drug candidates, ATI-50001 and ATI-50002. With respect to A-101 high-concentration hydrogen peroxide compositions including A-101 40% and 45% Topical Solutions, our issued patents begin to expire in 2022, subject to any applicable patent term extension that may be available in a particular country. Our intellectual property portfolio also contains a U.S., a European and other foreign country, patent applications directed to, among other things, formulations and methods of use for high concentration hydrogen peroxide compositions, including A-101, 40% and 45% Topical Solutions and a single-use, self-contained, pre-filled, disposable pen-type applicator for use with such formulations. Our pending U.S., European and other foreign country patent applications, if they issue as

patents, would be expected to expire in 2035, subject to any applicable patent term adjustment or extension that may be available in a particular country. With respect to our JAK inhibitor drug candidates ATI-50001 and ATI-50002, the issued U.S. and foreign patents expire between 2023 and 2030, subject to any applicable patent term extension that may be available in a particular country. With respect to certain novel JAK 3 inhibitors, the issued U.S. patent and foreign patent applications, if issued, begin to expire in 2030. Our intellectual property portfolio also contains issued patents and pending applications directed to, among other things, the use of JAK inhibitors for treating hair loss disorders that expire, or are expected to expire, in 2031, subject to any applicable patent term adjustment or extension that may be available in a particular country.

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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:

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A-101 40% Topical Solution for the Treatment of Seborrheic Keratosis

Overview

We are developing A-101 40% Topical Solution 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. In the first quarter of 2016, we initiated two multi-center, randomized, double blinded, vehicle-controlled Phase 3 clinical trials and one open label Phase 3 clinical trial of A-101 40% Topical Solution in patients with SK. In November 2016, we announced positive top-line results from the two pivotal Phase 3 clinical trials, which are summarized below. Based on these results, we submitted an NDA for A-101 40% Topical Solution for the treatment of SK to the FDA in February 2017, and we intend to submit an MAA in the European Union in the second half of 2017. If approved, A-101 40% Topical Solution would become the first FDA-approved drug for the treatment of SK.

Clinical Development

The following table summarizes our three completed Phase 3 clinical trials of A-101 40% Topical Solution:

Name of Trial and Number of Subjects Enrolled	Lesion Area	Date Completed	Trial Design	Trial Objective
SEBK-301 (n=450)	Trunk, Extremities and Face	November 2016	Multi-center, randomized, double-blind, vehicle-controlled, parallel group Four target lesions At least one lesion on face and one lesion on the trunk or extremities treated Duration: 106 days	Efficacy of A-101 40% Topical Solution vs. vehicle control
		October 2016		

SEBK-302 (n=487)	Trunk, Extremities and Face		Multi-center, randomized, double-blind, vehicle-controlled, parallel group Four target lesions At least one lesion on face and one lesion on the trunk or extremities treated Duration: 106 days	Efficacy of A-101 40% Topical Solution vs. vehicle control
SEBK-303 (n=147)	Trunk, Extremities and Face	November 2016	Multi-center open-label trial Four target lesions treated Duration: 148 days	Evaluate the safety of A-101 40% Topical Solution

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Phase 3 Clinical Trial of A-101 40% Topical Solution in Subjects with Seborrheic Keratosis on the Trunk, Extremities and Face (SEBK-301)

Trial Design

We commenced a Phase 3 clinical trial in February 2016 that was a multi-center, randomized, double-blind, vehicle-controlled, parallel group trial designed to evaluate the safety and efficacy of A-101 40% Topical Solution and a topical solution vehicle control. We completed the trial in November 2016. We enrolled 450 subjects in the trial at 17 sites in the United States, and 446 subjects completed the trial. Two of the 450 subjects withdrew from the trial due to serious adverse events not related to the study medication, and two additional subjects did not complete the study because they did not have enough time to participate. Of the 450 subjects who were enrolled in the trial, 223 subjects received A-101 40% Topical Solution, and 227 subjects received the vehicle control. The age of the subjects ranged from 42 to 90, with a mean age of 69. Of the 450 subjects who were enrolled in the trial, 186 were male, 264 were female and 440 were Caucasian, with a variety of skin types. Inclusion criteria included a clinical diagnosis of stable, clinically typical SK and four appropriate SK target lesions on the subject's trunk, extremities and face with at least one target lesion on the trunk or extremities and at least one target lesion on the face, each of a specified size and thickness.

The evaluation period consisted of 15 weeks after initial treatment. At the first visit, the investigator identified four eligible SK target lesions, including at least one target lesion on each subject’s face and at least one target lesion on each subject’s trunk or extremities for treatment. During the second visit, or baseline, which occurred on Day 1 of the evaluation period, eligible subjects were randomized to receive either the vehicle control or A-101 40% Topical Solution, and the applications were performed by non-evaluating 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 A-101 40% Topical Solution 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 a comparison between the treatment groups based on the proportion of randomized subjects with all four target lesions judged to be clear using the Physician's Lesion Assessment, or PLA, score at the end of the trial. The PLA score is a method we have developed and validated to measure the severity of lesions and uses a scale ranging from zero to three. A secondary endpoint of the trial compared the treatment groups based on the proportion of randomized subjects with at least three out of four target lesions judged to be clear using the PLA score at the end of the trial. A PLA score of zero represented no visible lesion; a PLA score of one represented near clearance, meaning 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.

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Efficacy Results

As shown in the graph below, for the primary endpoint, the proportion of randomized subjects with all four target lesions judged to be clear using the PLA score, we observed statistically significant improvements for A-101 40% Topical Solution as compared to the vehicle. At Day 106, 4.0% of the subjects receiving A-101 40% Topical Solution achieved total clearance, or a PLA score of zero, for all four target lesions, while no subjects in the vehicle control group achieved total clearance for all four target lesions. These results were statistically significant with a p-value of less than 0.002. P-value is a conventional statistical method for measuring the statistical significance of clinical results. A p-value of less than 0.05 is generally considered to represent statistical significance, meaning that there is a less than five percent likelihood that the observed results occurred by chance.

In addition, we measured the percentage of subjects who achieved total clearance at Day 106 for at least three out of the four target lesions, the results of which are presented below. At Day 106, 13.5% of the subjects receiving A-101 40% Topical Solution achieved total clearance of at least three out of the four target lesions, while no subjects in the vehicle control group achieved total clearance of at least three out of the four target lesions. These results were statistically significant, with a p-value of less than 0.0001.

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We also measured the percentage of subjects who achieved either total clearance or near clearance, represented by a PLA score of either zero or one at the end of the trial, of all target lesions on the trunk, extremities and face as well as just on the face, the results of which are presented below. The mean per-subject percent of target lesions on the face, trunk and extremities achieving either total clearance or near clearance at the end of the study for those subjects who completed the study protocol, or the per patient population, was 47.5% for the group receiving A-101 40% Topical Solution compared to 10.2% in the vehicle control group. These results were statistically significant, with a p-value of less than 0.0001. The mean per-subject percent of target lesions just on the face achieving either total clearance or near clearance at the end of the study for all subjects regardless of study protocol compliance, or the intent to treat population, was 64.4% for the group receiving A-101 40% Topical Solution compared to 15.0% in the vehicle control group. These results were statistically significant, with a p-value of less than 0.0001.

Safety Results

A-101 40% Topical Solution was generally well tolerated. Treatment-emergent adverse events were reported by 99 subjects, 45 in the vehicle group and 54 in the A-101 40% Topical Solution group. Six subjects in the vehicle group had seven serious adverse events, or SAEs, and four subjects in the A-101 40% Topical Solution group had four SAEs. The SAEs were all considered not to be related to the study medication. Two subjects, one in each treatment group, discontinued the study due to a serious adverse event. Most treatment-emergent adverse events were considered to be mild or moderate in intensity. However, only one of the adverse events considered to be severe in intensity, application site pain, was determined by the investigator to be related to the trial medication.

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Phase 3 Clinical Trial of A-101 40% Topical Solution in Subjects with Seborrheic Keratosis on the Trunk, Extremities and Face (SEBK-302)

Trial Design

We commenced a Phase 3 clinical trial in January 2016 that was a multi-center, randomized, double-blind, vehicle-controlled, parallel group trial designed to evaluate the safety and efficacy of A-101 40% Topical Solution and a topical solution vehicle control. We completed the trial in October 2016. We enrolled 487 subjects in the trial at 17 sites in the United States, and 479 subjects completed the trial. None of the 487 subjects enrolled withdrew from the trial due to adverse events, however; eight subjects did not complete the trial. Of the 487 subjects who were enrolled in the trial, 244 subjects received A-101 40% Topical Solution, and 243 subjects received the vehicle control. The age of the subjects ranged from 45 to 91, with a mean age of 69. Of the 487 subjects who were enrolled in the trial, 203 were male, 284 were female and 477 were Caucasian, with a variety of skin types. Inclusion criteria included a clinical diagnosis of stable, clinically typical SK and four appropriate SK target lesions on the subject's trunk, extremities and face with at least one target lesion on the trunk or extremities and at least one target lesion on the face, each of a specified size and thickness.

The evaluation period consisted of 15 weeks after initial treatment. At the first visit, the investigator identified four eligible SK target lesions, including at least one target lesion on each subject’s face and at least one target lesion on each subject’s trunk or extremities for treatment. During the second visit, or baseline, which occurred on Day 1 of the evaluation period, eligible subjects were randomized to receive either the vehicle control or the 40% concentration of A-101, and the applications were performed by non-evaluating staff. No applications were made at visit 3 on Day 8. At Day 22, any target lesion that met the retreatment criteria received a second application of A-101 40% Topical Solution 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 proportion of randomized subjects with all four target lesions judged to be clear using the PLA score at the end of the trial. A secondary endpoint of the trial was the proportion of randomized subjects with at least three out of four target lesions judged to be clear using the PLA score at the end of the trial.

Efficacy Results

As shown in the graph below, for the primary endpoint, the proportion of randomized subjects with all four target lesions judged to be clear using the PLA score, we observed statistically significant improvements as compared to the vehicle for A-101 40% Topical Solution. At Day 106, 7.8% of the subjects receiving A-101 40% Topical Solution achieved total clearance of all four target lesions, while no subjects in the vehicle control group achieved total clearance. The results for the active treatment group were statistically significant with a p-value of less than 0.0001.

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In addition, we measured the percentage of subjects who achieved total clearance at Day 106 for at least three out of the four target lesions, the results of which are presented below. At Day 106, 23% of the subjects receiving A-101 40% Topical Solution achieved total clearance of at least three out of the four target lesions, while no subjects in the vehicle control group achieved total clearance. These results were statistically significant, with a p-value of less than 0.0001.

We also measured the percentage of subjects who achieved either total clearance or near clearance of all target lesions on the face, trunk and extremities as well as just on the face, the results of which are presented below. The mean per-subject percent of target lesions on the face, trunk and extremities achieving either total clearance or near clearance at the end of the study for the per patient population was 54.3% for the group receiving A-101 40% Topical Solution compared to 4.7% in the vehicle control group. These results were statistically significant, with a p-value of less than 0.0001. The mean per-subject percent of target lesions just on the face achieving either total clearance or near clearance at the end of the study for the intent to treat population was 62.8% for the group receiving A-101 40% Topical Solution compared to 6.2% in the vehicle control group. These results were statistically significant, with a p-value of less than 0.0001.

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Safety Results

A-101 40% Topical Solution was generally well tolerated. Treatment-emergent adverse events were reported by 89 subjects, 43 in the vehicle group and 46 in the A-101 40% Topical Solution group. Four subjects in the vehicle group had four SAEs, and six subjects in the A-101 40% Topical Solution group had ten SAEs. None of the SAEs reported by subjects were considered to be related to the study medication, and there were no subjects who discontinued the trial due to an adverse event. Most treatment-emergent adverse events were considered to be mild or moderate in intensity.

Phase 3 Clinical Trial of A-101 40% Topical Solution in Subjects with Seborrheic Keratosis on the Trunk, Extremities and Face (SEBK-303)

Trial Design and Objective

We commenced a Phase 3 clinical trial in February 2016 that was an open-label clinical trial designed to evaluate the safety of A-101 40% Topical Solution in treating SK lesions. The trial evaluated the safety of A-101 40% Topical Solution by tabulating adverse events, local skin reactions, clinical laboratory tests, and vital signs of subjects receiving A-101 40% Topical Solution. We completed the trial in November 2016. We enrolled 147 adult subjects in the trial at ten sites in the United States. None of the 147 subjects enrolled withdrew from the trial due to adverse events; however, eight subjects did not complete the trial. The age of the subjects ranged from 35 to 94, with a mean of 68 years. Of the 147 subjects enrolled in the trial, 100 of the subjects were female and 47 were male, and the majority of subjects were Caucasian. Inclusion criteria included a clinical diagnosis of stable clinically typical SK and at least four appropriate SK target lesions.

The evaluation period consisted of 21weeks after initial treatment. At the first visit, the investigator identified four target lesions on the trunk, extremities or face for treatment. During a second visit, or baseline, which occurred on Day 1 of the evaluation period, lesions on each subject were treated with A-101 40% Topical Solution, and the applications were performed by non-evaluating staff. No applications were made at visit 3 on Day 8. At visits 4, 6 and 8, on Days 22, 43 and 64, respectively, any target lesions that met the retreatment criteria received additional applications of A-101 40% Topical Solution. No applications were made after visit 8 on Day 64. All target lesions were treated a maximum of four times. The subjects were evaluated at multiple times through visit 12 on Day 148.

Safety Results

In the open-label trial, we observed that four applications of A-101 40% Topical Solution were well-tolerated. Treatment-emergent adverse events were reported by 25 subjects. None of the adverse events reported were considered to be serious, and no subjects discontinued the study due to an adverse event. All treatment-emergent adverse events were considered to be mild or moderate in intensity.

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A-101 45% Topical Solution for Treatment of Common Warts

Phase 2 Clinical Trial

In December 2015, we commenced a Phase 2 clinical trial in which we evaluated 40% and 45% concentrations of A-101 for the treatment of common warts. This double-blinded, randomized Phase 2 trial was conducted at 6 sites in the United States and was designed to evaluate the safety, tolerability and dose-response of two concentrations of A-101 compared to a vehicle control consisting of placebo. Subjects were randomized in three equal groups to receive either A-101 topical solution at either the 40% or 45% concentration, or placebo. The primary endpoint for this trial was the mean change in the PWA score at the end of the study. The PWA score is a four-point scale of the investigators assessment of the severity of a target wart at a particular time point. We completed this Phase 2 clinical trial in August 2016. In this Phase 2 clinical trial, in which 90 patients completed an eight-week treatment period, we observed statistically significant improvements in the mean change in the PWA score and in complete clearance of common warts in subjects treated with the 45% concentration of A-101 compared to placebo. In mid-2017, we plan to commence two additional Phase 2 clinical trials of A-101 45% Topical Solution to assess the dose frequency as a treatment for common warts in adult and pediatric populations.

ATI-50001 and ATI-50002 for Alopecia Areata

We are developing ATI-50001 and ATI-50002, as well as other JAK inhibitor compounds, as potential treatments for hair loss associated with the autoimmune skin disease known as AA and potentially for other dermatological conditions. AA is typically characterized by patchy, non-scarring hair loss on the scalp and body. More severe forms of AA include alopecia totalis and alopecia universalis. Treatment options for the less severe, patchy forms of AA include corticosteroids, either topically applied or injected directly into the scalp where the bare patches are located, and the induction of an allergic reaction at the site of hair loss using a topical contact sensitizing agent, an approach known as topical immunotherapy. The same treatment options are utilized for the more severe forms of AA, although utilization of these treatment options for the more severe forms of AA is limited due to limited efficacy, side effects, and their impracticality for use on extensive surface areas. We are developing ATI-50001 as an oral treatment for alopecia totalis and alopecia universalis and ATI-50002 as a topical treatment for patchy AA. We submitted an investigational new drug application, or IND, to the FDA for ATI-50001 in October 2016 and we completed a Phase 1 clinical trial to evaluate the pharmacokinetic and pharmacodynamic properties of this drug candidate in the first quarter of 2017. We plan to initiate a Phase 2 clinical trial for ATI-50001, for the treatment of alopecia totalis and alopecia universalis, in the second half of 2017. We plan to submit an IND to the FDA for ATI-50002 in mid-2017, and to commence a Phase 2 clinical trial for this drug candidate in the second half of 2017.

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Manufacturing

We do not have any manufacturing facilities or personnel. We rely on third parties for the manufacture of preclinical and clinical supplies for all of our drug candidates. We also will rely on third parties for the commercial manufacture of A-101 40% Topical Solution if it receives marketing approval. We have entered into an exclusive, ten-year, automatically renewable supply agreement with PeroxyChem LLC, or PeroxyChem, to provide hydrogen peroxide, the active pharmaceutical ingredient, or API, that can be used in A-101 40% Topical Solution 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 40% Topical Solution 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.

In addition, we have engaged third parties for the supply and assembly of the pen-type applicator for A-101 40% Topical Solution, as well as the assembly, labeling and packaging of the finished drug product used in our Phase 3 clinical trials and for commercial purposes if A-101 40% Topical Solution is approved for marketing. Some of the services and components required for the manufacture and assembly of the pen-type applicator for A-101 40% Topical Solution were purchased from third-party manufacturers on a purchase order basis and do not have supply arrangements in place.

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 marketing approval for, our lead drug candidate, A-101 40% Topical Solution for the treatment of SK.

Commercialization

For A-101 40% Topical Solution, we expect to retain U.S. commercial rights and to establish collaborations with third parties to commercialize A-101 40% Topical Solution outside the United States. We have begun developing our sales, marketing and product distribution capabilities for A-101 40% Topical Solution ahead of any potential drug approval in order to support a commercial product launch. If we commercialize A-101 40% Topical Solution, 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 50 to 60 sales representatives would allow us to reach the approximately 5,000 dermatologists in the United States with the highest potential for using A-101 40% Topical Solution, who we estimate will continue to account for over 70% of in-office SK treatments 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.

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We believe dermatologists will be inclined to adopt A-101 40% Topical Solution 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. In addition, since A-101 40% Topical Solution 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.

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, biotechnology 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 40% Topical Solution, 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 40% Topical Solution for the treatment of SK, we are aware of the following companies that are developing treatments for SK: BioLineRx Ltd. is developing an over-the-counter drug candidate targeting multiple skin conditions, including SK; Skincential Sciences, Inc. currently markets a line of cosmetic products targeting skin conditions, including SK; and Epipharm, AG is developing a topical drug candidate targeting multiple skin conditions, including SK. We are also aware of early research being conducted with Akt inhibitors as a potential

treatment for SK. None of these products have been approved by the FDA for the treatment of SK in the United States.

With respect to A-101 45% Topical Solution for the treatment of common warts, we are aware of the following companies that are developing treatments for common warts: Nielsen BioSciences is developing a drug candidate for the treatment of common warts; BioLineRx Ltd. is developing an over-the-counter drug candidate targeting multiple skin conditions, including common warts; Cutanea Lifesciences, Inc. is developing a drug candidate for the treatment of common warts; and RXi Pharmaceuticals, Inc. is also developing a drug candidate for the treatment of common warts. In addition, other drugs have been used off-label as treatments for common warts. We could also encounter competition from over-the-counter treatments for common warts.

With respect to ATI-50001 and ATI-50002 for the treatment of AA, we anticipate competing with sensitizing agents such as diphencyprone, or DPCP, and topical, intralesional and systemic corticosteroids, which have been found to occasionally reduce symptoms of AA. Other treatments utilized for patchy AA include anthralin and minoxidil solution. We may also compete with companies developing chemical agents to be used in topical immunotherapies, as well as companies developing biologics, immunosuppressive agents, laser therapy, phototherapy, other JAK inhibitors and prostaglandin analogues to treat AA.

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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 40% Topical Solution 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 candidates, 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.

With respect to A-101 40% and 45% Topical Solution, we do not currently rely on licenses to any third party's intellectual property. We own two U.S. patents that include claims that cover the use of high-concentration hydrogen peroxide of at least 23%, including A-101 40% and 45% Topical Solution for the alleviation of SK and acrochordons. The patents in Australia, New Zealand and India include claims that cover the use of high-concentration hydrogen peroxide of at least 23%, including A-101 40% and 45% Topical Solution, for the alleviation of various skin conditions including SK, acrochordons, corns, tags, acne, warts and rosacea. The patents in Germany, the United Kingdom, Mexico and Singapore include claims that cover the use of high-concentration hydrogen peroxide of at least 23%, including A-101 40% and 45% Topical Solution for the alleviation of acrochordons. The issued patents relating to the use of A-101 40% and 45% Topical Solution begin to expire in 2022, subject to any applicable patent term extension that may be available in a particular country.

Our pending U.S., European and other foreign patent applications are directed to various formulations comprising high-concentration hydrogen peroxide, including A-101 40% and 45% Topical Solution 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. Any claims that issue from these applications will expire in 2035, subject to any applicable patent term adjustment or extension that may be available in a particular country.

With respect to ATI-50001 and ATI-50002, which we exclusively licensed from Rigel in the field of dermatology multiple families of patents and applications relating to these compounds and the uses thereof. In particular, we exclusively licensed patents and applications with claims that specifically cover the composition of matter for these compounds in the United States, the European Union, and other major foreign markets. The issued patents specifically directed to these compounds begin to expire in 2030, subject to any applicable patent term extension that may be available in a particular country. We also exclusively licensed applications in the United States, Australia, Canada, Europe and Japan with claims that cover the use of these compounds for the treatment of alopecia areata. Any claims that issue from these applications will expire in 2034, subject to any applicable patent term adjustment or extension that may be available in a particular country. We also licensed a family of patents and applications that relate to ATI-50001 and ATI-50002 that expire in 2023, subject to any applicable patent term extension that may be available in a particular country.

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We also exclusively license patents and applications from Columbia University relating to the use of JAK inhibitors to induce hair growth and treat hair loss disorders, including AA and AGA. In particular, we exclusively license a U.S. patent with claims directed to the use of a third-party JAK inhibitor for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth, which expires in 2031. We also exclusively license patents and applications with claims directed to the use of certain JAK1, JAK2 or JAK3 inhibitors for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth in the U.S., Europe, Japan and South Korea. Any claims that issue from the pending applications begin to expire in 2031, subject to any applicable patent term adjustment or extension that may be available in a particular country. In addition, we exclusively license PCT applications directed to methods of inducing hair growth with JAK1, JAK2 or JAK3 inhibitors and biomarkers for AA, which if claims issue, would expire in 2036, subject to any applicable patent term adjustment or extension that may be available in a particular country.

With respect to the JAK inhibitors that we license from other third parties, we exclusively license in the field of dermatology a family of applications relating to certain novel JAK 3 inhibitors and methods of use. In particular, we exclusively license a U.S. patent and pending applications in the U.S., Canada and Europe, with claims directed to the use of these specific JAK 3 inhibitors to inhibit activity of JAK 3 in a patient, which patent expires in 2030, subject to any applicable patent term extension that may be available. We also exclusively license a U.S. and a PCT application relating to the specific JAK 3 inhibitors and methods of use, including treating AA, AGA, and vitiligo, which, if they were to issue as patents, would expire in 2036, subject to any applicable patent term adjustment or extension that may be available in a particular country.

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.

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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 40% Topical Solution and A-101 45% Topical Solution. 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 marketing approval for and commercialize A-101 40% Topical Solution and A-101 45% Topical Solution in various countries throughout the world. 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 40% Topical Solution in our Phase 2 clinical trial. There are no remaining potential milestone payments under the assignment agreement. Under the finder's services agreement, we made a one-time milestone payment of $0.3 million in February 2016 upon the dosing of the first human subject with A-101 40% Topical Solution in our Phase 3 clinical trial, and we are obligated to make additional milestone payments of up to $1.0 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 40% Topical Solution 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.

License Agreement with Rigel

In August 2015, we entered into an exclusive, worldwide license and collaboration agreement with Rigel for the development and commercialization of products containing two specified JAK inhibitors, ATI-50001 and ATI-50002. Under this agreement, we intend to develop these JAK inhibitors for the treatment of AA and potentially for other dermatological conditions. We paid Rigel an upfront non-refundable payment of $8.0 million and have agreed to make aggregate payments of up to $80.0 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional $10.0 million to Rigel upon the achievement of a second set of development milestones. With respect to any products we commercialize under the agreement, we will pay Rigel quarterly tiered royalties on our annual net sales of each product at a high single-digit percentage of annual net sales, subject to specified reductions, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified countries under specified circumstances, ten years from the first commercial sale of such product.

The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach. We may also terminate the agreement without cause at any time upon advance written notice to Rigel. Rigel, after consultation with us, will be responsible for maintaining and prosecuting the patent rights, and we will have final decision-making authority regarding such patent rights for a product in the United States and the European Union. To the extent that we jointly develop intellectual property, we will confer and decide which party will be responsible for filing, prosecuting and maintaining those patent rights. The agreement also establishes a joint steering committee composed of an equal number of representatives for each party, which will monitor progress of the development of products.

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Stock Purchase Agreement with Vixen Pharmaceuticals, Inc.

On March 24, 2016, we entered into a stock purchase agreement with Vixen Pharmaceuticals, Inc., or Vixen, and JAK1, LLC, JAK2, LLC and JAK3, LLC, all together with Vixen, the Selling Stockholders, and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the representative of the Selling Stockholders. Pursuant to the stock purchase agreement, we acquired all shares of Vixen's capital stock from the Selling Stockholders, the Vixen Acquisition. Following the Vixen Acquisition, Vixen became a wholly-owned subsidiary of us. Pursuant to the stock purchase agreement, we paid $0.6 million upfront and issued an aggregate of 159,420 shares of our common stock to the Selling Stockholders. We are obligated to make annual payments of $0.1 million on March 24th of each year, through March 24, 2022, with such amounts being creditable against specified future payments that may be paid under the stock purchase agreement.

Under the stock purchase agreement, we agreed to use commercially reasonable efforts to develop and commercialize at least one product for the treatment of AA in humans and at least one product for the treatment of AGA in humans, in each case for commercial sale and distribution throughout the United States and such other areas of the world as we determine to be commercially prudent. In the event we do not comply with these obligations, we are obligated to license, on a non-exclusive basis, certain intellectual property rights related to the products to the Selling Stockholders or their designee, on terms to be mutually agreed to by the parties, among other rights exercisable by the Selling Stockholders.

We are obligated to make aggregate payments of up to $18.0 million to the Selling Stockholders upon the achievement of specified pre-commercialization milestones for three products in the United States, the European Union and Japan, and aggregate payments of up to $22.5 million upon the achievement of specified commercial milestones. With respect to any commercialized products covered by the stock purchase agreement, we are obligated to pay low single-digit royalties on net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. If we sublicense any of Vixen's patent rights and know-how acquired pursuant to the stock purchase agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

The stock purchase agreement contains customary representations, warranties and covenants of each party, and we and the Selling Stockholders have agreed to indemnify each other, subject to certain exceptions and limitations, for breaches of such representations, warranties and covenants. Subject to specified exceptions and extensions in some cases, the representations and warranties survive until September 2017.

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License Agreement with Columbia University

As a result of the Vixen Acquisition, we became party to the Exclusive License Agreement, by and between Vixen and the Trustees of Columbia University in the City of New York, or Columbia, dated as of December 31, 2015, or the Columbia License Agreement. Pursuant to the Columbia License Agreement, Vixen was granted an exclusive, worldwide license under specified Columbia patent rights and a non-exclusive, worldwide license under specified Columbia know-how in all fields to develop and commercialize a product that otherwise infringes a Columbia patent right or uses Columbia know-how. Vixen's rights to this Columbia intellectual property cover the use of specified JAK inhibitor compounds for the potential treatment of AA, AGA and other dermatological conditions.

We are obligated to pay Columbia an annual license fee of $10,000, subject to specified adjustments for patent expenses incurred by Columbia and creditable against any royalties that may be paid under the Columbia License Agreement. We are also obligated to pay up to an aggregate of $11.6 million upon the achievement of specified commercial milestones, including specified levels of net sales of products covered by Columbia patent rights and/or know-how, and royalties at a sub-single-digit percentage of annual net sales of products covered by Columbia patent rights and/or know-how, subject to specified adjustments. If we sublicense any of Columbia's patent rights and know-how acquired pursuant to the Columbia License Agreement, we will be obligated to pay Columbia a portion of any consideration received from such sublicenses in specified circumstances. The royalties, as determined on a country-by-country and product-by-product basis, are payable until the date that all of the patent rights for that product have expired, the expiration of any market exclusivity period granted by a regulatory body or, in specified circumstances, ten years from the first commercial sale of such product.

We have agreed to use commercially reasonable efforts to develop and commercialize at least one product. In the event we do not comply with this obligation, Columbia has the option to terminate the license or convert the exclusive patent license to a non-exclusive patent license. Further, in the event we do not comply with our obligations under the Vixen stock purchase agreement to develop and commercialize products, our rights under the Columbia License Agreement may revert to a party to be designated by the Selling Stockholders. Columbia is responsible for maintaining and prosecuting the patent rights, giving due consideration to our reasonable comments related thereto.

The Columbia License Agreement terminates on the date of expiration of all royalty obligations thereunder unless earlier terminated by either party for a material breach, subject to a specified cure period. We may also terminate the Columbia License Agreement without cause at any time upon advance written notice to Columbia.

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 40% Topical Solution, 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 40% Topical Solution 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.

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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 an 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, pharmacology, toxicity and formulation. 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.

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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 an 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 an NDA requesting approval to market the product. The submission of an 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 an 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.

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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 an 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.

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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, or NCE. A drug is an NCE 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 an NCE 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, dosage forms 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 an NDA. However, an applicant submitting an 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.

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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 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.

In the European Economic Area, or EEA, which is composed of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA.

There are two types of MAs:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency, or EMA, and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the EU. Under the Centralized Procedure, the maximum timeframe for the evaluation of a marketing authorization application is 210 days (excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP). Accelerated evaluation might be granted by the CHMP in exceptional cases, when the authorization of a medicinal product is of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. Under the accelerated procedure, the standard 210 days review period is reduced to 150 days.
- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA, this National MA can be recognized in another Member States through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure.

In the EEA, upon receiving marketing authorization, new chemical entities generally receive eight years of data exclusivity and an additional two years of market exclusivity. If granted, data exclusivity prevents regulatory authorities in the European Union from referencing the innovator's data to assess a generic application. During the

additional two-year period of market exclusivity, a generic marketing authorization can be submitted, and the innovator's data may be referenced, but no generic product can be marketed until the expiration of the market exclusivity. However, there is no guarantee that a product will be considered by the European Union's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

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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 transparency 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, or 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 $10,781.40 and $21,562.80 for each separate false claim, the

potential for exclusion from participation in federal healthcare programs, and, although the federal civil 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 the healthcare fraud statute 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.

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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 transparency in 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, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws 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.

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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 and 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; 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, as a condition for their outpatient drugs to be covered under Medicare Part D, must agree to offer 50% point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period. 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 meant to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services.

Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in January 2017, Congress adopted a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the Affordable Care Act. Following the passage of the Budget Resolution, in March 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, or the AHCA, which, if enacted, would amend or repeal significant portions of the Affordable Care Act. Among other changes, the AHCA would repeal the annual fee on certain brand prescription drugs and biologics imposed on manufacturers and importers, eliminate the 2.3% excise tax on medical devices, eliminate penalties on individuals and employers that fail to maintain or provide minimum essential coverage, and create refundable tax credits to assist individuals in buying health insurance. The AHCA would also make significant changes to Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements.

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 in 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 2025, 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. More recently, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products. For example, there have been several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of drugs under Medicare and reform government program reimbursement methodologies for drug products.

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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. Additional legislative actions may be taken in the future which may change current regulations, guidance and interpretations. The impact of such actions on our business, if any, cannot presently be determined.

The Hatch Waxman Amendments to the FDC Act

Orange Book Listing

In seeking approval for a drug through an 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 an 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 listed all patents that are eligible for listing in the Orange Book in our NDA for A-101 40% Topical Solution.

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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 40% Topical Solution 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 40% Topical Solution 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 45% Topical Solution 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.

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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. The Medicare Access and CHIP Reauthorization Act of 2015, or MACRA, ended the use of the statutory formula, and provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule through 2019, but no annual update from 2020 through 2025. MACRA also introduced a merit based incentive bonus program for Medicare physicians beginning in 2019. At this time it is unclear how the introduction of the merit based incentive program will impact overall physician reimbursement under the Medicare program.

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 December 31, 2016, we had 31 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.

Information about Segments

We currently operate in one business segment. Our singular focus is identifying, developing and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. See “Note 2—Summary of Significant Accounting Policies—Segment Data” to our consolidated financial statements contained in Part II, Item 8 of this Annual Report.

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. Our telephone number is (484) 324-7933. We completed our initial public offering in October 2015 and our common stock is listed on the NASDAQ Global Select Market under the symbol “ACRS”.

Available Information

Our internet website address is www.aclaristx.com. In addition to the information contained in this Annual Report, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. The public may read and copy the materials we file with the SEC at the SEC’s Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Additionally the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC’s website is www.sec.gov.

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Item 1A. Risk Factors

Our business is subject to numerous risks. You should carefully consider the following risks and all other information contained in this Annual Report, as well as general economic and business risks, together with any other documents we file with the SEC. If any of the following events actually occur or risks actually materialize, it 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.

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 biotechnology company with limited operating history. Since inception, we have incurred significant net losses. We incurred net losses of $48.1 million and $20.6 million for the years ended December 31, 2016 and 2015, respectively. As of December 31, 2016, we had an accumulated deficit of $90.9 million. We have financed our operations since inception from sales of our convertible preferred stock and, beginning with our initial public offering in October 2015, from public offerings and a private placement of our common 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 date to the development of our drug candidates, including preclinical studies and clinical trials. 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:

- pursue marketing approvals for A-101 40% Topical Solution for the treatment of SK and for any other drug candidates that successfully complete clinical trials;
- continue our ongoing clinical trials evaluating A-101 45% Topical Solution for the treatment of common warts;
- initiate and continue clinical trials of our other drug candidates, including ATI-50001 and ATI-50002 for the treatment of AA;
- seek to discover and develop additional drug candidates;
- establish a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize any drug candidates for which we may obtain marketing 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, investor relations 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 marketing approval, and manufacturing, marketing and selling any drug candidates for which we may obtain marketing 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 marketing approval for 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 marketing 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.

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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 marketing approvals for our drugs, 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.

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 marketing approval and achieve product sales. We expect to continue to incur significant expenses and operating losses over the next several years as we conduct clinical trials of our drug candidates and seek marketing approval for A-101 40% Topical Solution for the treatment of SK. 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 in the near term, if at all. If we obtain marketing approval for A-101 40% Topical Solution 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, 2016, we had cash, cash equivalents and marketable securities of $174.1 million. We believe that our existing cash and cash equivalents as of the date of this Annual Report will enable us to fund our operating expenses and capital expenditure requirements for a period greater than 12 months from the date of this report based on our current operating assumptions. These assumptions 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 of obtaining marketing approval for A-101 40% Topical Solution for the treatment of SK;
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the progress and results of the Phase 2 clinical trials evaluating A-101 45% Topical Solution 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 ATI-50001 and ATI-50002;
- 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 40% Topical Solution 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 40% Topical Solution for the treatment of SK. If we receive marketing approval for A-101 40% Topical Solution for this indication, we expect to incur significant commercialization expenses related to product manufacturing, sales, marketing and distribution,

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depending on where we choose to commercialize. Additional funds may not be available on a timely basis, on commercially acceptable 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, 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, developing A-101 40% Topical Solution for the treatment of SK, including undertaking preclinical studies and conducting clinical trials, and acquiring new drug candidates and related intellectual property. A-101 40% Topical Solution, A-101 45% Topical Solution and ATI-50001 are our only drug candidates for which we have completed clinical trials. We have not yet demonstrated our ability to successfully obtain marketing 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

If we are unable to successfully develop, receive marketing approval for and commercialize our 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 have invested substantially all of our efforts and financial resources in the development of A-101 40% Topical Solution for the treatment of SK, as well as 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 in the near term, if ever, will depend heavily on their successful development, marketing approval and eventual commercialization of these drug candidates. The success of A-101 40% Topical Solution or any other drug candidates that we develop, including A-101 45% Topical Solution, ATI-50001 and ATI-50002, 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 marketing approval;

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- receipt of timely 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 40% Topical Solution or any other drug candidates, if approved;
- the prevalence and severity of adverse events experienced with 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 treatment procedures; and
- maintaining a continued acceptable safety, tolerability and efficacy profile of our drugs following approval.

Whether marketing 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 marketing approval. If, following submission, our NDA for A-101 40% Topical Solution 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 40% Topical Solution or any of our other drug candidates will never obtain marketing 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 marketing approval. Before obtaining 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.

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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 marketing 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 marketing approval for indications or patient populations that are not as broad as intended or desired;
- obtain marketing 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.

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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 marketing 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 rely on and expect to continue 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 marketing approval and commercialization, increase our costs or necessitate the abandonment or limitation of the development of some of our drug candidates.

Before obtaining marketing 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.

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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 approval to market 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, and may also require additional testing, FDA notification or FDA approval. 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. 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 40% Topical Solution 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.

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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 products for sale at competitive prices;
- 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 40% Topical Solution 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 products together with other medications.

If we are unable to establish sales, marketing and distribution capabilities for A-101 40% Topical Solution or any other drug candidate that may receive marketing approval, we may not be successful in commercializing those drug candidates if and when they are approved.

We do not have sales or marketing infrastructure. To achieve commercial success for A-101 40% Topical Solution 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.

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

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

With respect to A-101 40% Topical Solution for the treatment of SK, we are aware of two biopharmaceutical companies developing drug candidates which target SK, and another company that currently markets a line of cosmetic products targeting skin conditions, including SK. We are also aware of early research being conducted with Akt inhibitors as a potential treatment for SK.

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

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than A-101 40% Topical Solution or any other drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for our drug, which could result in our competitors establishing a strong market position before we are able to enter the market.

With respect to ATI-50001 and ATI-50002 for the treatment of AA, we anticipate competing with sensitizing agents such as diphencyprone, or DPCP, and topical, intralesional and systemic corticosteroids, which have been found to occasionally reduce symptoms of AA. Other treatments utilized for patchy AA include anthralin and minoxidil solution. We may also compete with companies developing chemical agents to be used in topical immunotherapies, as well as companies developing biologics, immunosuppressive agents, laser therapy, phototherapy, other JAK inhibitors and prostaglandin analogues to treat AA.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical and clinical development, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant

competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

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 40% Topical Solution 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 40% Topical Solution depends on the extent to which patients will be willing to pay out of pocket for the in-office procedure using these drug candidates.

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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 45% Topical Solution 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 rates 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. MACRA ended the use of the statutory formula and provided for a 0.5% annual increase in payment rates under the Medicare Physician Fee Schedule through 2019, but no annual update from 2020 through 2025. MACRA also introduced a merit based incentive bonus program for Medicare physicians beginning in 2019. At this time it is unclear how the introduction of the merit based incentive program will impact overall physician reimbursement under the Medicare program. Any resulting decrease in payment under the merit based reimbursement system 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.

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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 $7.5 million in product liability insurance coverage in the aggregate, with a per incident limit of $7.5 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 marketing 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.

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Risks Related to Our Dependence on Third Parties

We will 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 engaged a CRO to conduct our Phase 3 clinical trials of A-101 40% Topical Solution and expect to engage a CRO to conduct clinical trials 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 marketing 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 marketing 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.

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We contract with third parties for the manufacture of our drug candidates 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 our drug candidates 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 all of our drug candidates for preclinical and clinical testing, as well as for commercial manufacture if any of our drug candidates, including A-101 40% Topical Solution, should receive marketing approval. For example, we have entered into an exclusive, ten-year, automatically renewable supply agreement with PeroxyChem, a manufacturer of hydrogen peroxide, to provide the active pharmaceutical ingredient that can be used in A-101 40% Topical Solution for the treatment of SK. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates at an acceptable cost and/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-parties to manufacture commercial supplies of any of our drug candidates, including A-101 40% Topical Solution, 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 40% Topical Solution; 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 the components of A-101 40% Topical Solution.

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.

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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 marketing 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 marketing 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.

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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.

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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 or our licensors were the first to make the inventions claimed in our patents or pending patent applications, or that we or our licensors were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our technology or drugs, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our patents or narrow the scope of our patent protection.

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

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

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

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In addition, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in loss of exclusivity or freedom to operate or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and drugs, or limit the duration of the patent protection of our technology and drugs. Our issued U.S. patents, with claims directed to treatment of SK and acrochordons with high-concentration hydrogen peroxide of at least 23%, including A-101 40% and 45% Topical Solutions, are scheduled to expire in 2022. Certain issued U.S. patents relating to our JAK inhibitors, ATI-50001 and ATI-50002, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to such JAK inhibitors, are scheduled to expire in 2030. The issued U.S. patent relating to our novel JAK 3 inhibitors is scheduled to expire in 2030. The issued U.S. and Japanese patents that we exclusively licensed from Columbia University with claims directed to the use of a third party JAK inhibitor for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth, expires in 2031. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

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

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

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

that have marketed high-concentration hydrogen peroxide solutions over the internet for the treatment of SK and warts. These parties do not appear to have regulatory authority, and we have not authorized them in any way to market these products. However, to date we have refrained from seeking to enforce our intellectual property rights against these third parties due to the transient nature of their activities.

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

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

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With respect to ATI-50001 and ATI-50002, if we do not elect to exercise our first right to do so, Rigel may enforce the licensed patents relating to ATI-50001 and ATI-50002 against any infringing third party in the field of dermatology. In addition, Rigel has the first right, but not the obligation, to enforce the licensed patents relating to ATI-50001 and ATI-50002 against any infringing party outside of the field of dermatology. In November 2015, we entered into an exclusive, worldwide license agreement with JAKPharm LLC, or JAKPharm, and Key Organics, LTD, or Key Organics, for the development and commercialization of products containing specified novel JAK inhibitors for any therapeutic, prophylactic, prognostic or diagnostic applications for use in any dermatological condition or disease. With respect to the licensed patents from JAKPharm and Key Organics, pursuant to our exclusive license agreement with JAKPharm and Key Organics, if we do not elect to exercise our first right to do so, JAKPharm and Key Organics may enforce the licensed patents relating to an infringement of the licensed JAK compounds against any infringing third party in the field of dermatology. In addition, JAKPharm and Key Organics has the right to enforce the licensed patents relating to an infringement of the licensed JAK compounds against any infringing party outside of the field of dermatology. With respect to the licensed patents from Columbia University, Columbia University has the first right to initiate, control and defend any proceedings related to the validity, enforceability or infringement of the licensed patent rights and in doing so, has no obligation to assert more than one licensed patent in one jurisdiction against a third party. With respect to the licensed patents from Columbia University, if Columbia University does not elect to exercise its first right to do so, we may enforce the licensed patent rights relating to an infringement of the licensed patent rights against any infringing third party.

If we breach our license agreement with Rigel, it could compromise our development and commercialization efforts for our JAK inhibitors ATI-50001 and ATI-50002.

In August 2015, we entered into an exclusive license agreement with Rigel, which grants us the rights to certain patent rights and other intellectual property owned by them relating to the JAK inhibitors ATI-50001 and ATI-50002 in the field of dermatology. If we materially breach or fail to perform any provision under this license agreement, including failure to make payments to Rigel when due for royalties and failure to use commercially reasonable efforts to develop and commercialize a JAK inhibitor, Rigel has the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed Rigel’s patent rights and other intellectual property would end. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under the license agreement with Rigel.

If we breach our license agreement with JAKPharm and Key Organics, it could compromise our development and commercialization efforts for certain of our JAK inhibitors.

In November 2015, we entered into an exclusive, worldwide license agreement with JAKPharm and Key Organics for the development and commercialization of products containing certain novel JAK inhibitors in the field of dermatology. If we materially breach or fail to perform any provision under our license agreement with JAKPharm and Key Organics, including failure to make payments to JAKPharm and Key Organics when due for royalties and failure to use commercially reasonable efforts to develop and commercialize a JAK inhibitor, JAK Pharm and Key Organics have the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed JAKPharm and Key Organics’ patent rights and other intellectual property would end. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights and other intellectual property licensed to us under the license agreement with JAKPharm and Key Organics.

If we breach our agreement with the Selling Stockholders of Vixen, it could compromise our development and commercialization efforts for our JAK inhibitors.

In March 2016, we entered into a stock purchase agreement with the stockholders of Vixen, pursuant to which we purchased all of the stock of Vixen and assumed its license agreement with Columbia University. If we fail to use commercially reasonable efforts to develop and commercialize a JAK inhibitor for AA and a JAK inhibitor for AGA, the license agreement with Columbia University will be transferred to the Selling Stockholders of Vixen following any adverse resolution of any dispute relating thereto. Upon the effective date of such transfer, our right to practice the licensed Columbia University patent rights and know-how would end.

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If we breach our agreement with Columbia University, it could compromise our development and commercialization efforts for our JAK inhibitors.

In March 2016, as part of the Vixen acquisition, we assumed a license agreement with Columbia University, which grants us the right under certain patent rights and know-how owned by Columbia University relating to the use of JAK inhibitors to treat hair-loss disorders. If we materially breach or fail to perform any provision under this license agreement, including failure to make payments to Columbia University when due for royalties and failure to use commercially reasonable efforts to develop and commercialize a licensed product, Columbia University has the right to terminate our license, and upon the effective date of such termination, our right to practice the licensed Columbia University patent rights and know-how would end. Any uncured, material breach under the license agreement could result in our loss of rights to practice the patent rights and know-how licensed to us under the license agreement, and, to the extent such patent rights and know-how relate to our JAK inhibitors, it could compromise our development and commercialization efforts for ATI-50001 or ATI-50002 or the novel JAK inhibitors licensed from JAKPharm and Key Organics.

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 40% Topical Solution for the treatment of SK is currently covered by patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. The use of A-101 45% Topical Solution for the treatment of warts is currently covered by issued patents in Australia, India and New Zealand, but not in the United States, European Union or other countries. Our JAK inhibitors, ATI-50001 and ATI-50002, are currently covered in patents and applications in the United States, the European Union, and other major foreign markets. Our novel JAK inhibitors licensed from JAKPharm and Key Organics are currently covered in a U.S. patent and in pending applications in the United States, Canada and Europe. Additionally, only one U.S. patent and one Japanese patent have issued in the patent portfolio licensed from Columbia University, which are directed to the use of certain third party JAK inhibitors for the treatment of hair loss disorders and applications are pending in the United States, Europe, Japan and South Korea. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our invention in such countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our drug candidates and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

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

We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful.

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

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. For example, we exclusively license intellectual property from Rigel in the field of

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dermatology related to our JAK inhibitors, ATI-50001 and ATI-50002. We also exclusively license intellectual property from JAKPharm and Key Organics in the field of dermatology related to other novel JAK inhibitors, and we also exclusively license intellectual property from Columbia University related to the use of JAK inhibitors for the treatment of hair loss disorders. 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.

Our third party licensors may develop JAK inhibitors, including those related to our drug candidates, outside of the field of dermatology.

We exclusively license intellectual property from Rigel and other third parties in order to develop, use, manufacture, sell and commercialize our JAK inhibitors in the field of dermatology. These third party licensors have retained the rights under such intellectual property to develop, use, manufacture, sell and commercialize the licensed JAK inhibitors outside of the field of dermatology. If any of these third party licensors were to commercialize such JAK inhibitors outside the field of dermatology, such a product could possibly be used off-label for a dermatology indication, which could negatively impact sales of our JAK inhibitor product candidates, if approved. Our licensors also retained the intellectual property rights to develop, use, manufacture, sell and commercialize other structurally similar JAK inhibitors. If such third parties commercialize a structurally similar JAK inhibitor, such a product could directly compete with our product candidates, if approved.

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. For example, we are aware of third parties that are pursuing broad claims directed to the use of JAK inhibitors for the treatment of AA. 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, our employees or our licensors have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

Many of our employees and our licensor's employees were previously employed at other biotechnology or pharmaceutical companies. Although we and our licensor try to ensure that our employees and our licensors' employees do not use the proprietary information or know-how of others in their work for us, we or our licensors may be subject to claims that these employees, our licensors 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.

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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 or our licensors 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 and our licensors are successful in prosecuting or defending against such claims, litigation could result in substantial costs and be a distraction to management.

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. Some 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. 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.

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The validity, scope and enforceability of any patents listed in the Orange Book that cover A-101 40%Topical Solution, A-101 45% Topical Solution and our JAK inhibitors can be challenged by competitors.

If A-101 40% Topical Solution, A-101 45% Topical Solution or one of our JAK inhibitors is approved by the FDA, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio, including those covering A-101 40% Topical Solution, A-101 45% Topical Solution or our JAK inhibitors, which could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement. For example, if a third party files an Abbreviated New Drug Application, or ANDA, for a generic drug containing A-101 40% Topical Solution, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved drug candidate; (2) the patents listed in the Orange Book have expired; (3) the listed patents have not expired, but will expire on a particular date and approval is sought after patent expiration; or (4) the listed patents are invalid or will not be infringed by the manufacture, use or sale of the third party's generic drug. A certification that the new drug will not infringe the Orange Book-listed patents for the applicable approved drug candidate, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with 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. patent, with claims directed to treatment of SK with A-101 40% Topical Solution, is scheduled to expire in 2022. Certain issued U.S. patents relating to our JAK inhibitors, ATI-50001 and ATI-50002, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to such JAK inhibitors, are scheduled to expire in 2030. The issued U.S. patent relating to the use of our novel JAK inhibitors licensed from JAKPharm and Key Organics is scheduled to expire in 2030. The issued U.S. and Japanese patents licensed from Columbia University relating to the use of a third party JAK inhibitor for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth, expire in 2031. 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 United States 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). This extension is limited to only one patent that covers the approved product. 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.

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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 preclinical data to obtain approval of competing products following our patent expiration and launch their product earlier than might otherwise be the case. For example, even if we obtain NCE exclusivity for A-101 40% Topical Solution, we could be subject to generic competition as early as the end of the applicable exclusivity period, if our patent portfolio does not have sufficient term or scope to prevent such generic competition.

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:

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others may be able to make formulations or compositions that are the same as or similar to A-101 40% and 45% Topical Solutions but that are not covered by the claims of the patents that we own;

- others may be able to make a JAK inhibitor that is similar to the JAK inhibitors we intend to commercialize that is not covered by the patents that we exclusively licensed and have the right to enforce;
- we, our licensor 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, our licensor 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.

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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 European Commission and EU Member State Competent Authorities 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.

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

We may seek marketing approval for A-101 40% Topical Solution 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.

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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 civil 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. Further, 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. 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, including, without limitation, the federal civil False Claims Act (that can be enforced through civil whistleblower or qui tam actions), and the civil monetary penalties law, which impose criminal and civil penalties, 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;

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- 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 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 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 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, individual imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws 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.

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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, among other things, 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.

Since its enactment there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the Affordable Care Act. In January 2017, President Trump signed an Executive Order directing federal agencies with authorities and responsibilities under the Affordable Care Act to waive, defer, grant exemptions from, or delay the implementation of any provision of the Affordable Care Act that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. Further, in January 2017, Congress adopted a budget resolution for fiscal year 2017, or the Budget Resolution, that authorizes the implementation of legislation that would repeal portions of the Affordable Care Act. Following the passage of the Budget Resolution, in March 2017, the U.S. House of Representatives introduced legislation known as the American Health Care Act, or the AHCA, which, if enacted, would amend or repeal significant portions of the Affordable Care Act. Among other changes, the AHCA would repeal the annual fee on certain brand prescription drugs and biologics imposed on manufacturers and importers, eliminate the 2.3% excise tax on medical devices, eliminate penalties on individuals and employers that fail to maintain or provide minimum essential coverage, and create refundable tax credits to assist individuals in buying health insurance. The AHCA would also make significant changes

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to Medicaid by, among other things, making Medicaid expansion optional for states, repealing the requirement that state Medicaid plans provide the same essential health benefits that are required by plans available on the exchanges, modifying federal funding, including implementing a per capita cap on federal payments to states, and changing certain eligibility requirements. While it is uncertain when or if the provisions in the AHCA will become law, or the extent to which any such changes may impact our business, it is clear that concrete steps are being taken to repeal and replace certain aspects of the Affordable Care Act.

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 2025 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.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drugs. In addition, there have been several recent Congressional inquiries and proposed bills designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the costs of drugs under Medicare and reform government program reimbursement methodologies for drug products. 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 40% Topical Solution, 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 40% Topical Solution 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.

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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 40% Topical Solution and A-101 45% Topical Solution. 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.

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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, legal 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 have entered into employment agreements with our executive officers, each of them may currently terminate their employment with us at any time. We do not maintain “key person” insurance for any of our executives or employees other than Dr. Walker and Mr. Powala.

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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 marketing 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 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 December 31, 2016, we had 31 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, 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, 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. We have adopted 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.

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Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not continue to develop or be sustained.

Prior to our initial public offering in October 2015, there was no public market for our common stock. Although our common stock is listed on The NASDAQ Global Select Market, we cannot assure you that an active trading market for our shares will continue to develop or be sustained. If an active market for our common stock does not continue to develop or is not sustained, it may be difficult for investors in our common stock to sell shares without depressing the market price for the shares or to sell the shares at all.

The trading price of the shares of our common stock has been and is likely to continue to be volatile.

Since our initial public offering, our stock price has been and is likely to continue to be volatile. The stock market in general and the market for biotechnology 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 any clinical trials we may conduct, or changes in the development status of our drug candidates;
- any delay in our regulatory filings for any of our drug candidates 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 marketing approval of our drug candidates;
- unanticipated serious safety concerns related to the use of A-101 40% Topical Solution 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 biotechnology 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.

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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 is influenced by the research and reports that equity research analysts publish about us or our business, our market and our competitors. Equity research analysts may elect not to initiate or continue to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. Even if we 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.

The issuance of additional stock in connection with financings, acquisitions, investments, our equity incentive plan or otherwise will dilute all other stockholders.

Our certificate of incorporation authorizes us to issue up to 100,000,000 shares of common stock and up to 10,000,000 shares of preferred stock with such rights and preferences as may be determined by our board of directors. Subject to compliance with applicable rules and regulations, we may issue our shares of common stock or securities convertible into our common stock from time to time in connection with a financing, acquisition, investment, our equity incentive plan or otherwise. Any such issuance could result in substantial dilution to our existing stockholders and cause the trading price of our common stock to decline.

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, the market price of our common stock could decline significantly.

In addition, we have filed registration statements on Form S-8 under the Securities Act registering the issuance of 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 are available for sale in the public market subject to vesting arrangements and exercise of options, and the restrictions of Rule 144 under the Securities Act in the case of our affiliates.

Additionally, certain holders of shares of our common stock, or their transferees, 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 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 some or all of our stockholders. For example, our board of directors has the authority to issue up to 10,000,000 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.

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

- only one of our three classes of directors is elected each year;
- stockholders are not entitled to remove directors other than by a 662/3% vote and only for cause;
- stockholders are not 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.

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own a substantial portion of our 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. The interests of this group of stockholders may not coincide with our interests or 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 report;

- 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 stockholder 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) December 31, 2020, (2) the last day of the fiscal year in which we have total annual gross revenue of at least $1.0 billion, (3) the last day of the fiscal year 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 (4) any date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

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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.

We are subject to the reporting requirements of the Exchange Act, 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, and 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. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

We may identify weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our consolidated 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 unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective. 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 SEC, or other regulatory authorities.

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, 2016, we had federal and state net operating loss carryforwards of $38.1 million for each, and federal research and development tax credit carryforwards of $1.5 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, 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.

We have broad discretion in the use of proceeds from our public offerings 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 have broad discretion over the use of proceeds from our public offerings in 2015 and 2016. 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 from those offerings to fund our research and development expenses and for working capital and general corporate purposes. Our failure to apply the net proceeds effectively could compromise our ability to pursue our strategy and we might not be able to yield a significant return, if any, on our investment of these net proceeds. Stockholders will not have the opportunity to influence our decisions on how to use the net proceeds from our offerings.

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We do not anticipate paying any cash dividends on our common stock in the foreseeable future and our stock may not appreciate in value.

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. There is no guarantee that shares of our common stock will appreciate in value or that the price at which our stockholders have purchased their shares will be able to be maintained.

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 have begun, and will continue, particularly after we cease to be an "emerging growth company," to incur significant additional legal, accounting and other costs. 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.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for certain litigation that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on our behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, (iii) any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, our

amended and restated certificate of incorporation or our amended and restated bylaws or (iv) any action asserting a claim governed by the internal affairs doctrine. The choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We currently sublease 13,200 square feet of space for our headquarters in Malvern, Pennsylvania. Our sublease has a term through November 30, 2019, 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. We also lease an additional 2,534 square feet of space, from a different landlord, in the same building as our headquarters. The lease for this additional space also has a term through November 30, 2019. 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

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additional or substitute space will be available as needed to accommodate any such expansion of our operations.

Item 3. Legal Proceedings

We are not subject to any material legal proceedings.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information for Common Stock

Our common stock commenced trading on the NASDAQ Global Select Market under the symbol "ACRS" on October 7, 2015. Prior to our initial public offering, there was no public market for our common stock. The following table sets forth for the periods indicated the high and low sales prices of our common stock as reported on the NASDAQ Global Select Market.

	High	Low
2016		
First Quarter	$ 27.94	$ 14.12
Second Quarter	23.58	16.86
Third Quarter	25.76	17.90
Fourth Quarter	31.80	20.15
2015		
Fourth Quarter (since October 7, 2015)	$ 33.88	$ 10.99

On March 14, 2017, the last reported bid price for our common stock was $30.48 per share.

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.

Stockholders

As of March 14, 2017, we had 26,088,866 shares of common stock outstanding held by 41 holders of record.

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Performance Graph

The following graph compares the performance of our common stock since October 7, 2015, the date on which our common stock commenced trading on the NASDAQ Global Select Market, with the performance of the NASDAQ Composite Index (U.S.) and the NASDAQ Biotechnology Index. The comparison assumes a $100 investment on October 7, 2015 in our common stock, the stocks comprising the NASDAQ Composite Index, and the stocks comprising the NASDAQ Biotechnology Index, and assumes reinvestment of the full amount of all dividends, if any. Historical stockholder return is not necessarily indicative of the performance to be expected for any future periods.

Comparison of Cumulative Total Return

Among Aclaris Therapeutics, Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index

The performance graph shall not be deemed to be incorporated by reference by means of any general statement incorporating by reference this Form 10-K into any filing under the Securities Act of 1933, as amended or the Exchange Act, except to the extent that we specifically incorporate such information by reference, and shall not otherwise be deemed filed under such acts.

Use of Proceeds from Initial Public Offering of Common Stock

On October 6, 2015, our Registration Statement on Form S-1, as amended (File No. 333-206437) was declared effective in connection with our initial public offering, pursuant to which we sold 5,750,000 shares of our common stock, including the full exercise of the underwriters' option to purchase additional shares, at a price to the public of $11.00 per share. The offering closed on October 13, 2015, and, as a result, we received net proceeds of $56.6 million (after underwriters' discounts and commissions of $4.4 million and additional offering related costs of $2.3 million). The joint managing underwriters of the offering were Jefferies LLC and Citigroup Global Markets Inc.

No expenses incurred by us in connection with our initial public offering were paid directly or indirectly to (i) any of our officers or directors or their associates, (ii) any persons owning 10% or more of any class of our equity securities, or (iii) any of our affiliates, other than payments in the ordinary course of business to officers for salaries and to non-employee directors as compensation for board or board committee service.

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There has been no material change in the planned use of proceeds from our initial public offering from that described in the final prospectus filed by us with the SEC on October 8, 2015 pursuant to Rule 424(b) of the Securities Act. Through December 31, 2016, we have not used any of the net proceeds, as we have used cash and marketable securities on hand as of the initial public offering date to fund the continued research and development of A-101 40% Topical Solution and our other drug candidates and for working capital and other general corporate purposes.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

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Item 6. Selected Consolidated Financial Data

The following selected consolidated statement of operations data for the years ended December 31, 2016, 2015 and 2014, and consolidated balance sheet data as of December 31, 2016 and 2015 is derived from our audited consolidated financial statements included within this Annual Report. The consolidated balance sheet data as of December 31, 2014 and 2013, and the consolidated statement of operations data for the year ended December 31, 2013 have been derived from our audited consolidated financial statements which are not included herein. Our historical results are not necessarily indicative of the results to be expected in the future. The selected financial data should be read together with Item 7. “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and in conjunction with the consolidated financial statements, related notes, and other financial information included elsewhere in this Annual Report.

	Year Ended December 31,			
	2016	2015	2014	2013
	(in thousands)			
Consolidated Statement of Operations Data:				
Revenue	$	$ —	$ —	$ —
Operating expenses:				
Research and development	33,476	15,339	6,507	3,488
General and administrative	15,091	5,328	2,026	1,769
Total operating expenses	48,567	20,667	8,533	5,257
Loss from operations	(48,567)	(20,667)	(8,533)	(5,257)
Other income, net	488	104	16	21
Net loss	(48,079)	(20,563)	(8,517)	(5,236)
Accretion of convertible preferred stock	-	(2,566)	(2,054)	(1,740)
Net loss attributable to common stockholders	$ (48,079)	$ (23,129)	$ (10,571)	$ (6,976)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.25)	$ (3.79)	$ (6.15)	$ (6.45)
Weighted average common shares outstanding, basic and diluted	21,415,733	6,107,042	1,720,082	1,081,347

	As of December 31,

	2016	2015	2014	2013
	(in thousands)			
Consolidated Balance Sheet Data:				
Cash, cash equivalents and marketable securities	$ 174,134	$ 92,038	$ 16,648	$ 14,126
Working capital (a)	132,333	84,969	14,883	13,019
Total assets	176,085	94,076	17,377	14,207
Convertible preferred stock	-	-	36,677	23,000
Total stockholders' equity (deficit)	169,490	92,521	(20,755)	(9,163)

(a) Working capital is defined as current assets minus current liabilities

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Item 7. 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 in conjunction with the consolidated financial statements and the related notes to those statements included later in this Annual Report. In addition to historical financial information, the following discussion contains forward looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. Our actual results and the timing of events could differ materially from those discussed in these forward looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report, particularly in "Item 1A. Risk Factors" and "Special Note Regarding Forward Looking Statements."

Overview

We are a clinical-stage biotechnology company focused on identifying, developing and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. Our lead drug candidate, A-101 40% Topical Solution, is a proprietary formulation of 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. In the first quarter of 2016, we initiated two multi-center, randomized, double blinded, vehicle-controlled Phase 3 clinical trials and one open label Phase 3 clinical trial of A-101 40% Topical Solution in patients with SK. In November 2016, we announced positive top-line results from the two pivotal Phase 3 clinical trials. Based on these results, we submitted a New Drug Application, or NDA, for A-101 40% Topical Solution for the treatment of SK to the U.S. Food and Drug Administration, or FDA, in February 2017, and we intend to submit a Marketing Authorization Application, or MAA, in the European Union in the second half 2017. We are also developing A-101 45% Topical Solution as a prescription treatment for common warts, also known as verruca vulgaris. Additionally, in 2015, we in-licensed exclusive, worldwide rights to certain inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions, including alopecia areata, androgenetic alopecia, or AGA, and vitiligo. In 2016, we acquired additional intellectual property rights for the development and commercialization of certain JAK inhibitors for specified dermatological conditions. We intend to continue to in-license or acquire additional drug candidates and technologies 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 40% Topical Solution for the treatment of SK, building our intellectual property portfolio, developing our supply chain and engaging in other discovery and clinical activities in dermatology. Through the date of this report, we have not generated any revenue and have financed our operations with sales of our convertible preferred stock, net proceeds from our initial public offering, or IPO, in October 2015, a private placement of our common stock in June 2016, and from a follow-on public offering of our common stock in November 2016. We do not expect to generate significant revenue unless and until we obtain marketing approval for and commercialize A-101 40% Topical Solution for the treatment of SK or one of our other current or future drug candidates.

Since our inception, we have incurred significant operating losses. Our net losses were $48.1 million, $20.6 million and $8.5 million for the years ended December 31, 2016, 2015 and 2014, respectively. As of December 31, 2016, we had an accumulated deficit of $90.9 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, seek marketing 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, we have incurred and expect to continue 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 commercially acceptable 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.

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License Agreement with Rigel

In August 2015, we entered into an exclusive, worldwide license and collaboration agreement with Rigel Pharmaceuticals, Inc., or Rigel, for the development and commercialization of products containing two specified JAK inhibitors. Under this agreement, we intend to develop these JAK inhibitors for the treatment of alopecia areata, or AA, and potentially for other dermatological conditions. We paid Rigel an upfront nonrefundable payment of $8.0 million in September 2015. In addition, we have agreed to make aggregate payments of up to $80.0 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional $10.0 million to Rigel upon the achievement of a second set of development milestones. With respect to any products we commercialize under the agreement, we will pay Rigel quarterly tiered royalties on our annual net sales of each product at a high single digit percentage of annual net sales, subject to specified reductions until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified countries under specified circumstances, 10 years from the first commercial sale of such product.

The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach. We may also terminate the agreement without cause at any time upon advance written notice to Rigel. Rigel, after consultation with us, will be responsible for maintaining and prosecuting the patent rights, and we will have final decision-making authority regarding such patent rights for a product in the United States and the European Union. To the extent that we jointly develop intellectual property, we will confer and decide which party will be responsible for filing, prosecuting and maintaining those patent rights. The agreement also establishes a joint steering committee composed of an equal number of representatives for each party, which will monitor progress in the development of products.

We accounted for the license and collaboration agreement with Rigel as an asset acquisition since the arrangement did not meet the definition of a business pursuant to the guidance prescribed in Accounting Standards Codification Topic 805, Business Combinations. Accordingly, we recorded the $8.0 million upfront payment as research and development expense in the year ended December 31, 2015. We will record contingent milestone payments and royalties as research and development expense or cost of revenues, respectively, in the period in which such liabilities are incurred.

We concluded the licensing arrangement with Rigel did not meet the definition of a business because the transaction principally resulted in its acquisition of intellectual property. As part of the transaction, we did not acquire employees, tangible assets, processes, protocols or operating systems. In addition, at the time of the acquisition, there were no activities being conducted related to the licensed patents. We expensed the acquired intellectual property asset upon acquisition because we will use it in our research and development activities and believe it has no alternative future uses.

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Stock Purchase Agreement with Vixen Pharmaceuticals, Inc. and License Agreement with Columbia University

On March 24, 2016, we entered into a stock purchase agreement with Vixen Pharmaceuticals, Inc., or Vixen, and JAK1, LLC, JAK2, LLC and JAK3, LLC, all together with Vixen, the Selling Stockholders, and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the representative of the Selling Stockholders. Pursuant to the Vixen Agreement, we acquired all shares of Vixen's capital stock from the Selling Stockholders, or the Vixen Acquisition. Following the Vixen Acquisition, Vixen became a wholly-owned subsidiary of us. Pursuant to the Vixen Agreement, we paid $0.6 million upfront and issued an aggregate of 159,420 shares of our common stock to the Selling Stockholders. We are obligated to make annual payments of $0.1 million on March 24th of each year, through March 24, 2022, with such amounts being creditable against specified future payments that may be paid under the Vixen Agreement.

We are obligated to make aggregate payments of up to $18.0 million to the Selling Stockholders upon the achievement of specified pre-commercialization milestones for three products in the United States, the European Union and Japan, and aggregate payments of up to $22.5 million upon the achievement of specified commercial milestones. With respect to any commercialized products covered by the Vixen Agreement, we are obligated to pay low single-digit royalties on net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. If we sublicense any of Vixen's patent rights and know-how acquired pursuant to the Vixen Agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

As a result of the transaction with Vixen, we became party to the Exclusive License Agreement, by and between Vixen and the Trustees of Columbia University in the City of New York, or Columbia, dated as of December 31, 2015, or the License Agreement. Under the License Agreement, we are obligated to pay Columbia an annual license fee of $10,000 subject to specified adjustments for patent expenses incurred by Columbia and creditable against any royalties that may be paid under the License Agreement. We are also obligated to pay up to an aggregate of $11.6 million upon the achievement of specified commercial milestones, including specified levels of net sales of products covered by Columbia patent rights and/or know-how, and royalties at a sub-single-digit percentage of annual net sales of products covered by Columbia patent rights and/or know-how, subject to specified adjustments. If we sublicense any of Columbia's patent rights and know-how acquired pursuant to the License Agreement, we will be obligated to pay Columbia a portion of any consideration received from such sublicenses in specified circumstances. The royalties, as determined on a country-by-country and product-by-product basis, are payable until the date that all of the patent rights for that product have expired, the expiration of any market exclusivity period granted by a regulatory body or, in specified circumstances, ten years from the first commercial sale of such product. The License Agreement terminates on the date of expiration of all royalty obligations thereunder unless earlier terminated by either party for a material breach, subject to a specified cure period. We may also terminate the License Agreement without cause at any time upon advance written notice to Columbia.

We accounted for the transaction with Vixen as an asset acquisition as the arrangement did not meet the definition of a business pursuant to the guidance prescribed in Accounting Standards Codification Topic 805, Business

Combinations. We concluded the transaction with Vixen did not meet the definition of a business because the transaction principally resulted in the acquisition of the License Agreement. We did not acquire tangible assets, processes, protocols or operating systems. In addition, at the time of the transaction, there were no activities being conducted related to the licensed patents. We expensed the acquired intellectual property as of the acquisition date on the basis that the cost of intangible assets purchased from others for use in research and development activities, and that have no alternative future uses, are expensed at the time the costs are incurred. Accordingly, we recorded the $0.6 million upfront payment, the fair value of the shares of common stock issued of $2.4 million, and the present value of the six non-contingent annual payments as research and development expense in the year ended December 31, 2016. Additionally, we will record as expense any contingent milestone payments or royalties in the period in which such liabilities are incurred.

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Other 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 40% Topical Solution 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.

In connection with the assignment agreement, we also entered into a finder's services agreement under which we have paid aggregate milestone payments of $0.5 million and have agreed to make aggregate payments of up to $1.0 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 40% Topical Solution or related products at a low single-digit percentage of net sales, as defined in the agreement.

In November 2015, we entered into an exclusive, worldwide license agreement with JAKPharm LLC, or JAKPharm, and Key Organics, LTD, or Key Organics, for the development and commercialization of products containing specified novel JAK inhibitors for any therapeutic, prophylactic, prognostic or diagnostic applications for use in any dermatological condition or disease. We made upfront non-refundable payments of $0.3 million and are obligated to make aggregate payments of up to $2.4 million upon the achievement of specified milestones, such as completion of clinical trials and filing of applications for regulatory approvals. With respect to any products we commercialize under the agreement, we will pay tiered royalties equal to a low to middle single-digit percentage of annual net sales, subject to specified reductions, as determined on a country-by-country and product-by-product basis, until the date that all of the patent rights for that product have expired, or in specified countries under specified circumstances, ten years from the first commercial sale of such product.

Components of Our Results of Operations

Revenue

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

Research and Development Expenses

Research and development expenses consist 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;
- depreciation of manufacturing equipment;
- payments made under agreements with third parties under which we have acquired or licensed intellectual property;
- expenses relating to regulatory activities, including filing fees paid to regulatory agencies; and
- laboratory materials and supplies used to support our research activities.

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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, continue to conduct pre-commercial activities related to A-101 40% Topical Solution for treatment of SK, and conduct clinical trials and prepare regulatory filings for our other 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 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 marketing approvals, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. We may never succeed in achieving marketing 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, 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 personnel costs, including stock-based compensation, expanded infrastructure and higher consulting, legal and tax-related services associated with maintaining compliance with Nasdaq and SEC, requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a public company. Additionally, if and when we believe a marketing 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 that drug candidate.

Interest Income

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

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Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States of America. The preparation of our consolidated 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 consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our 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 preclinical development activities and clinical trials are performed pursuant to quotes and contracts with multiple vendors, including research institutions and CROs, that conduct and manage such activities on our behalf. Many of the contracts with our vendors require advance payments; while others invoice us in arrears for services performed, or on a pre-determined schedule, or upon the successful enrollment of patients, or when contractual milestones are met. We record expenses for preclinical development activities and clinical trials based upon estimates of the total cost of the services to be provided by the vendor and the time period over which the vendor is to perform those services. Estimates of research and development expenses included in our consolidated financial statements are based on facts and circumstances known to us at that time. The financial terms of our agreements are subject to negotiation, vary from contract to contract, and may result in uneven payment flows. There may be times when payments made to a vendor exceed the level of services provided, resulting in a prepayment for work to be performed. We may confirm the accuracy of our estimates with the service providers, or make adjustments to our estimates based upon new or updated facts and circumstances, as necessary. For example, if the timing and/or cost of services to be performed is materially different from our previous estimates, we would make a prospective adjustment for the change in our estimates in the period in which we become aware of the new cost and/or timing. Although we do not expect our estimates to be materially different from actual amounts 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 estimates of research and development expenses.

Stock-Based Compensation

We measure the compensation expense of stock-based awards granted to employees and directors using the grant date fair value of the award. We have issued stock options and restricted stock unit, or RSU, awards with service-based vesting conditions, as well as with performance-based vesting conditions. We have not issued awards that include market-based conditions. For service-based awards we recognize stock-based compensation expense on a straight-line basis over the requisite service period. For performance-based awards we recognize stock-based compensation expense on a straight-line basis over the requisite service period beginning in the period that it becomes probable the performance conditions will occur. At each balance sheet date, we evaluate whether any performance conditions related to a performance-based award have changed. The effect of any change in performance conditions would be recognized as a cumulative catch-up adjustment in the period such change occurs, and any remaining unrecognized compensation expense would be recognized on a straight-line basis over the remaining requisite service period. The impact of forfeitures is recognized in the period in which they occur.

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We initially measure the compensation expense of stock-based awards granted to consultants using the grant date fair value of the award. We recognize compensation expense over the period during which services are rendered by the consultant. At the end of each financial reporting period prior to the completion of services being rendered, we re-measure the compensation expense related to these awards using the then current fair value of our common stock for RSUs, or based upon updated assumptions in the Black-Scholes option-pricing model for stock option awards.

We estimate the fair value of each stock option grant using the Black-Scholes option-pricing model. We estimate expected volatility based on historical volatility of a set of peer companies, which are publicly traded, and we expect to continue to do so until we have adequate historical data regarding the volatility of our own publicly-traded stock price. The expected term of our stock options has been determined using the "simplified" method for awards that qualify as "plain vanilla" options. The expected term of stock options we 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. We use an expected dividend yield of zero because we have not paid cash dividends to date, and have no intention of paying cash dividends in the future. Prior to our IPO, we valued our common stock using a hybrid method which used market approaches to estimate our enterprise value. The hybrid method used was a probability-weighted expected return method which was a scenario-based methodology that estimated the fair value of our common stock based upon an analysis of future values for the company assuming various outcomes. The hybrid method used calculated equity values using an option pricing model in one or more of scenarios, and also considered the rights of each class of stock.

The fair value of each restricted RSU is measured using the closing price of our common stock on the date of grant.

Income Taxes

Since our inception in 2012, we have not recorded U.S. federal or state income tax benefits for the net operating losses we have incurred in each year or for our earned research and development tax credits, due to our uncertainty of realizing a benefit from those items. As of December 31, 2016, we had federal and state net operating loss carryforwards of $38.1 million each, both of which begin to expire in 2032. As of December 31, 2016, we also had federal research and development tax credit carryforwards of $1.5 million, which begin to expire in 2032, and we had no state research and development tax credit carryforwards.

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Results of Operations

Comparison of Years Ended December 31, 2016 and 2015

The following table summarizes our results of operations for the years ended December 31, 2016 and 2015:

	Year Ended December 31, 2016	2015	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	33,476	15,339	18,137
General and administrative	15,091	5,328	9,763
Total operating expenses	48,567	20,667	27,900
Loss from operations	(48,567)	(20,667)	(27,900)
Other income, net	488	104	384
Net loss	$ (48,079)	$ (20,563)	$ (27,516)

Research and Development Expenses

Research and development expenses were $33.5 million for the year ended December 31, 2016, compared to $15.3 million for the year ended December 31, 2015. The increase of $18.1 million was primarily attributable to a $10.2 million increase in costs associated with the development of A-101 40% Topical Solution for the treatment of SK, an increase of $7.3 million in preclinical development expenses related to our JAK inhibitor technology, a $0.5 million increase in costs related to the development of A-101 45% Topical Solution for the treatment of common warts, an increase of $2.2 million in payroll-related expenses due to increased headcount, and an increase of $2.0 million in stock-based compensation expense. The increases noted above were partially offset by a decrease of $4.6 million in licensing expenses as we incurred $3.4 million of expenses associated with the Vixen acquisition in the year ended December 31, 2016, compared to $8.0 million of expense resulting from the upfront payment made to Rigel for the ATI-50001 and ATI-50002 JAK inhibitor drug candidates during the year ended December 31, 2015.

General and Administrative Expenses

General and administrative expenses were $15.1 million for the year ended December 31, 2016, compared to $5.3 million for the year ended December 31, 2015. The increase of $9.8 million was primarily attributable to increases of $2.2 million in payroll-related expenses due to increased headcount, $3.2 million in stock-based compensation expense, $0.4 million in legal and patent expenses related to the Vixen acquisition, $1.5 million in professional fees associated with being a public company, and $1.5 million in market research expenses related to pre-commercial activities for A-101 40% Topical Solution, as well as a $0.3 million one-time milestone payment made during the year ended December 31, 2016 pursuant to the finder's services agreement related to A-101.

Other Income, net

The increase in other income, net was primarily due to interest income received from higher invested balances of marketable securities as a result of funds received from our IPO in October 2015, our private placement in June 2016 and our follow-on public offering in November 2016.

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Comparison of Years Ended December 31, 2015 and 2014

The following table summarizes our results of operations for the years ended December 31, 2015 and 2014:

	Year Ended December 31, 2015	2014	Change
	(in thousands)		
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	15,339	6,507	8,832
General and administrative	5,328	2,026	3,302
Total operating expenses	20,667	8,533	12,134
Loss from operations	(20,667)	(8,533)	(12,134)
Other income, net	104	16	88
Net loss	$ (20,563)	$ (8,517)	$ (12,046)

Research and Development Expenses

Research and development expenses were $15.3 million for the year ended December 31, 2015, compared to $6.5 million for the year ended December 31, 2014. The increase of $8.8 million was primarily attributable to an $8.0 million upfront payment to Rigel in connection with our license of rights to specified JAK inhibitors and related intellectual property. In addition, regulatory and clinical consulting expenses increased by $0.4 million in connection with our Phase 2 trials of A-101 40% Topical Solution, and depreciation expense increased by $0.4 million resulting from an equipment impairment charge of $0.3 million recorded in the year ended December 31, 2015.

General and Administrative Expenses

General and administrative expenses were $5.3 million for the year ended December 31, 2015, compared to $2.0 million for the year ended December 31, 2014. The increase of $3.3 million was primarily attributable to increases of $0.8 million in payroll related costs mainly associated with increased headcount, $0.6 million in stock-based compensation, $0.5 million in market research expenses, $0.5 million in patent filing and prosecution costs related to the JAK inhibitor technology and $0.8 million in professional fees for accounting and auditing services, investor relations, insurance and board fees associated with becoming a public company.

Other Income, net

Other Income, net was composed primarily of interest income, which increased during the year ended December 31, 2015 as a result of higher invested cash and marketable securities balances following our IPO.

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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 convertible preferred stock, from our IPO in October 2015, our private placement in June 2016, and our follow-on offering in November 2016.

As of December 31, 2016, we had cash, cash equivalents and marketable securities of $174.1 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view towards 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 and sublease obligations and contingent obligations under intellectual property licensing arrangements, as described below under “Contractual Obligations and Commitments”.

Initial Public Offering

On October 13, 2015, we closed our IPO in which we sold 5,750,000 shares of common stock at a price to the public of $11.00 per share, for aggregate gross proceeds of $63.3 million. We paid underwriting discounts and commissions of $4.4 million, and we also incurred expenses of $2.3 million in connection with the IPO. As a result, the net offering proceeds to us, after deducting underwriting discounts and commissions and offering expenses, were $56.6 million.

Private Placement

On June 2, 2016, we closed a private placement in which we sold an aggregate of 1,081,082 shares of common stock at a price of $18.50 per share, for gross proceeds of $20.0 million. We incurred placement agent fees of $1.3 million, and expenses of $0.2 million in connection with the private placement. As a result, the net offering proceeds received by us, after deducting placement agent fees and transaction expenses, were $18.5 million.

Follow-On Public Offering

On November 23, 2016, we closed our follow-on public offering in which we sold 4,600,000 shares of common stock at a price to the public of $22.75 per share, for aggregate gross proceeds of $104.7 million. We paid underwriting discounts and commissions of $6.3 million, and we also incurred expenses of $0.2 million in connection with the offering. As a result, the net offering proceeds received by us, after deducting underwriting discounts, commissions and offering expenses, were $98.2 million.

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Cash Flows

The following table summarizes our cash flows for each of the periods presented:

	Year Ended December 31,		
	2016	2015	2014
	(In thousands)		
Net cash used in operating activities	$ (34,603)	$ (20,369)	$ (7,636)
Net cash used in investing activities	(61,903)	(76,951)	(1,779)
Net cash provided by financing activities	116,826	96,414	10,584
Net increase (decrease) in cash and cash equivalents	$ 20,320	$ (906)	$ 1,169

Operating Activities

During the year ended December 31, 2016, our operating activities used $34.6 million of cash, primarily resulting from our net loss of $48.1 million partially offset by cash provided by changes in our operating assets and liabilities of $4.5 million and by non-cash expenses of $9.0 million. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2016 consisted primarily of a $4.3 million increase in accounts payable and accrued expenses. The increase in accounts payable and accrued expenses was primarily due to expenses incurred, but not yet paid, in connection with preclinical development expenses related to our JAK inhibitor technology and the timing of vendor invoicing and payments. In addition, we had $1.7 million of employee-related accruals as of December 31, 2016, compared to $0 as of December 31, 2015. The increase in employee-related accruals resulted from bonuses earned in 2016 which were paid after December 31, 2016, while all bonuses earned in 2015 were paid before December 31, 2015. Non-cash expenses of $9.0 million primarily included $6.1 million related to share-based compensation expense, and $2.8 million resulting from the Vixen acquisition.

During the year ended December 31, 2015, our operating activities used $20.4 million of cash, primarily resulting from our net loss of $20.6 million and net cash used in our operating assets and liabilities of $1.1 million, partially offset by non-cash increases of $0.9 million in stock-based compensation expense and a $0.3 million write-down of equipment held for sale to net realizable value. Net cash used in changes in our operating assets and liabilities during the year ended December 31, 2015 consisted primarily of a $1.3 million increase in prepaid expenses and other current assets and a $0.4 million decrease in accounts payable, partially offset by a $0.6 million increase in accrued expenses. The increase in accrued expenses was primarily due to the timing of invoices for licensing fees and legal expenses relating to our wholly-owned subsidiary. The increase in prepaid expenses and other current assets was primarily due to prepayments for clinical trials and prepayments of insurance policies.

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, 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 million 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 40% Topical Solution. The increase in prepaid expenses and other current assets was primarily due to a prepayment for manufacturing scale up expenses.

Investing Activities

During the year ended December 31, 2016, we used cash of $61.9 million in investing activities, consisting of purchases of marketable securities of $148.8 million and purchases of equipment of $0.2 million, partially offset by proceeds from sales and maturities of marketable securities of $87.1 million.

During the year ended December 31, 2015, we used cash of $77.0 million in investing activities, consisting of purchases of marketable securities of $82.5 million and purchases of equipment of $0.5 million, partially offset by proceeds from sales and maturities of marketable securities of $6.1 million.

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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.

Financing Activities

During the year ended December 31, 2016, net cash provided by financing activities was $116.8 million, consisting primarily of $18.5 million of net proceeds received from the private placement of our common stock in June 2016 and net proceeds of $98.2 million received from our follow-on public offering of common stock in November 2016.

During the year ended December 31, 2015, net cash provided by financing activities was $96.4 million, consisting of $39.8 million of net proceeds received from our issuance of Series C convertible preferred stock in August 2015 and net proceeds of $56.6 million received from our initial public offering of common stock in October 2015.

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 convertible preferred stock in September 2014.

Funding Requirements

We plan to focus in the near term on the development, marketing approval and potential commercialization of A-101 40% Topical Solution 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 40% Topical Solution for the treatment of SK and continue research and development of A-101 45% Topical Solution for the treatment of common warts and ATI-50001 and ATI-50002 for the treatment of AA, and potentially for other dermatological conditions, as well as for development of other JAK inhibitor compounds. In addition, we plan to continue to invest in discovery efforts to explore additional drug candidates, 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 A-101 40% Topical Solution or our other drug candidates currently in 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.

As a publicly traded company, we have incurred and will continue to 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 were not applicable to us prior to our IPO. We expect ongoing compliance with these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

We believe our existing cash, cash equivalents and marketable securities are sufficient to fund our operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of our consolidated financial statements based on our current operating assumptions including the completion of our Phase 2 clinical trials for A-101 45% Topical Solution for the treatment of common warts and the continued development of ATI-50001 and ATI-50002 as potential treatments for AA. These assumptions 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 40% Topical Solution, if we receive marketing approval, and to pursue in-licenses or acquisitions of other drug candidates. If we receive marketing approval for A-101 40% Topical Solution, 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 commercially acceptable 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.

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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 the rights of 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 marketing 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, 2016 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	$ 1,052	$ 350	$ 702	$ —	$ —
Vixen annual commitment	600	100	200	200	100
Total	$ 1,652	$ 450	$ 902	$ 200	$ 100

We occupy office space in Malvern, Pennsylvania under two operating lease agreements both of which have terms through November 2019.

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 40% Topical Solution 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 $1.0 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 40% Topical Solution or related products at a low single-digit percentage of net sales, as defined in the agreement.

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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.

Under a license agreement with Rigel that we entered into in August 2015, we have agreed to make aggregate payments of up to $80.0 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional $10.0 million to Rigel upon the achievement of a second set of development milestones. With respect to any products we commercialize under the agreement, we will pay Rigel quarterly tiered royalties on our annual net sales of each product developed using the licensed JAK inhibitors at a high single digit percentage of annual net sales, subject to specified reductions.

Under a commercial license agreement with JAKPharm and Key Organics that we entered into in November 2015, we have agreed to make aggregate payments of up to $2.4 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals. We will pay an annual maintenance fee of $50,000, to be credited against any milestone fees or royalties paid in each calendar year. With respect to any products we commercialize under the agreement, we will pay tiered royalties at a low to mid-single-digit percentage of annual net sales, subject to specified reductions, as determined on a country-by-country and product-by-product basis, until the date that all of the patent rights for that product have expired, or in specified countries under specified circumstances, ten years from the first commercial sale of such product.

Under a stock purchase agreement with the Selling Stockholders of Vixen, we are obligated to make aggregate payments of up to $18.0 million upon the achievement of specified pre-commercialization milestones for three products covered by the Vixen patent rights in the United States, the European Union and Japan, and aggregate payments of up to $22.5 million upon the achievement of specified commercial milestones for products covered by the Vixen patent rights. We are also obligated to make a payment of $0.1 million on March 24th of each year, through March 24, 2022, which amounts are creditable against any specified future payments that may be paid under the stock purchase agreement. With respect to any products we commercialize under the stock purchase agreement, we are obligated to pay low single-digit percentage of annual net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. If we sublicense any of the patent rights and know-how acquired pursuant to the stock purchase agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

Under a license agreement with Columbia, we are obligated to pay an annual license fee of $10,000, subject to specified adjustments for patent expenses incurred by Columbia and creditable against any royalties that may be paid under the license agreement. We are also obligated to pay up to an aggregate of $11.6 million upon the achievement of specified commercial milestones, including specified levels of net sales of products covered by Columbia patent rights and/or know-how, and royalties at a sub-single-digit percentage of annual net sales of products covered by

Columbia patent rights and/or know-how, subject to specified adjustments. If we sublicense any of Columbia's patent rights and know-how acquired pursuant to the license agreement, we will be obligated to pay Columbia a portion of any consideration Vixen receives from such sublicenses in specified circumstances.

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 SEC.

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Recently Issued and Adopted Accounting Pronouncements

In January 2017, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2017-01, Business Combinations-Clarifying the Definition of a Business (Topic 805). The amendments in this ASU provide a screen to determine when a set of acquired assets and/or activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The amendments in this ASU will reduce the number of transactions that meet the definition of a business. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those years, and early adoption will be permitted. We are assessing the potential impact of ASU 2017-01 on our consolidated financial statements.

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326). This ASU introduces a new model for recognizing credit losses on financial instruments based upon estimated expected credit losses. ASU 2016-13 will apply to loans, accounts receivable, financial assets measured at amortized cost and at fair value through other comprehensive income, loan commitments and certain off-balance sheet credit exposures. ASU 2016-13 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those years, and early adoption will be permitted. We are assessing the potential impact of ASU 2016-13 on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. This ASU requires all tax effects of share-based payment settlements to be recorded through the income statement. Currently, tax benefits in excess of compensation cost, or “windfalls”, are recorded in equity, and tax deficiencies, or “shortfalls”, are recorded to equity to the extent of previous windfalls, and then to the income statement. In addition, under the new guidance, companies will be permitted to make a policy election to recognize the impact of forfeitures either when they occur, or on an estimated basis. Finally, this update simplifies withholding requirements to allow companies to withhold up to an employee’s maximum tax rate without resulting in liability classification for the award. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, and early adoption is permitted. We adopted the provisions of this standard early, the impact of which on our consolidated financial statements was not significant.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard establishes a right-of-use, or ROU, model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The new standard is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. We are currently evaluating the potential impact of the adoption of this standard.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in this update revise the accounting related to the classification and measurement of investments in equity securities and the presentation of certain fair value changes for financial liabilities measured at fair value. The amendments are effective for annual reporting periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. We are currently evaluating the potential impact of the adoption of this standard.

In November 2015, the FASB, issued ASU 2015- 17, Balance Sheet Classification of Deferred Taxes. The amendments in this update simplify the presentation of deferred income taxes to require that deferred tax liabilities and assets are classified as noncurrent in a statement of financial position. The amendments are effective for annual reporting periods beginning after December 15, 2016 and interim reporting periods within those annual periods. Early application is permitted. We have adopted the provisions of ASU 2015-17 early, the impact of which on our consolidated financial statements was not significant.

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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.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are exposed to market risk related to changes in interest rates. Our cash equivalents and marketable securities consist of money market funds, asset-backed securities, commercial paper, 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.

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Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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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 consolidated balance sheets and the related consolidated statements of operations and comprehensive loss, of convertible preferred stock and stockholders' (deficit) equity and of cash flows, present fairly, in all material respects, the financial position of Aclaris Therapeutics, Inc. and its subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2016 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

March 15, 2017

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ACLARIS THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2016	2015
Assets		
Current assets:		
Cash and cash equivalents	$ 30,171	$ 9,851
Marketable securities	107,051	75,017
Prepaid expenses and other current assets	1,334	1,656
Total current assets	138,556	86,524
Marketable securities	36,912	7,170
Property and equipment, net	481	360
Deferred offering costs	116	—
Other assets	20	22
Total assets	$ 176,085	$ 94,076
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,845	$ 810
Accrued expenses	3,378	745
Total current liabilities	6,223	1,555
Other liabilities	372	—
Total liabilities	6,595	1,555
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at December 31, 2016 and December 31, 2015	—	—
Common stock, $0.00001 par value; 100,000,000 shares authorized at December 31, 2016 and December 31, 2015; 26,059,181 and 20,157,503 shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	—	—
Additional paid in capital	260,671	135,503
Accumulated other comprehensive loss	(269)	(149)
Accumulated deficit	(90,912)	(42,833)
Total stockholders' equity	169,490	92,521
Total liabilities and stockholders' equity	$ 176,085	$ 94,076

The accompanying notes are an integral part of these consolidated financial statements.

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ACLARIS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31, 2016	2015	2014
Revenue	$ —	$ —	$ —
Operating expenses:			
Research and development	33,476	15,339	6,507
General and administrative	15,091	5,328	2,026
Total operating expenses	48,567	20,667	8,533
Loss from operations	(48,567)	(20,667)	(8,533)
Other income, net	488	104	16
Net loss	(48,079)	(20,563)	(8,517)
Accretion of convertible preferred stock	—	(2,566)	(2,054)
Net loss attributable to common stockholders	$ (48,079)	$ (23,129)	$ (10,571)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.25)	$ (3.79)	$ (6.15)
Weighted average common shares outstanding, basic and diluted	21,415,733	6,107,042	1,720,082
Other comprehensive loss:			
Unrealized gain (loss) on marketable securities, net of tax of $0	105	(148)	(9)
Foreign currency translation adjustments	(225)	5	—
Total other comprehensive loss	(120)	(143)	(9)
Comprehensive loss	$ (48,199)	$ (20,706)	$ (8,526)

The accompanying notes are an integral part of these consolidated financial statements.

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ACLARIS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CONVERTIBLE PREFERRED STOCK

AND STOCKHOLDERS' EQUITY (DEFICIT)

(In thousands, except share data)

	Series A, B and C Convertible Preferred Stock		Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Par Value				
Balance at December 31, 2013	20,890,000	$ 23,000	2,730,427	$ —	$ —	$ 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	27,341,057	36,677	2,730,427	—	—	(6)	(20,749)	(20,755)
Issuance of Series C convertible preferred stock, net of issuance costs of $136	12,944,984	39,864	—	—	—	—	—	—

Issuance of common stock in connection with IPO, net of offering costs of $2,272	—	—	5,750,000	—	56,550	—	—	56,550
Issuance of common stock upon conversion of convertible preferred stock	(40,286,041)	(78,305)	11,677,076	—	78,305	—	—	78,305
Unrealized loss on marketable securities	—	—	—	—	—	(148)	—	(148)
Foreign currency translation adjustment	—	—	—	—	—	5	—	5
Stock-based compensation expense	—	—	—	—	891	—	—	891
Accretion of redeemable convertible preferred stock to redemption value	—	1,764	—	—	(243)	—	(1,521)	(1,764)
Net loss	—	—	—	—	—	—	(20,563)	(20,563)
Balance at December 31, 2015	—	—	20,157,503	—	135,503	(149)	(42,833)	92,521
Issuance of common stock in connection with Vixen acquisition	—	—	159,420	—	2,355	—	—	2,355
Issuance of common stock in connection with private placement, net of offering costs of $1,453	—	—	1,081,082	—	18,547	—	—	18,547
Issuance of common stock in connection with follow-on public offering, net of offering costs of $6,492	—	—	4,600,000	—	98,158	—	—	98,158
Exercise of stock options and vesting of RSUs	—	—	61,176	—	4	—	—	4
Unrealized gain on marketable securities	—	—	—	—	—	105	—	105
	—	—	—	—	—	(225)	—	(225)

Foreign currency translation adjustment	—	—	—	—	—	(269)	—	(269)
Stock-based compensation expense	—	—	—	—	6,104	—	—	6,104
Net loss	—	—	—	—	—	—	(48,079)	(48,079)
Balance at December 31, 2016	—	$ —	26,059,181	$ —	$ 260,671	$ (269)	$ (90,912)	$ 169,490

The accompanying notes are an integral part of these consolidated financial statements.

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ACLARIS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

(In thousands)

	Year Ended December 31,		
	2016	2015	2014
Cash flows from operating activities:			
Net loss	$ (48,079)	$ (20,563)	$ (8,517)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation expense	120	90	12
Stock-based compensation expense	6,104	891	27
Write-down of property and equipment held for sale	216	289	—
Non-cash charges related to Vixen acquisition	2,784	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other assets	(8)	(1,269)	(152)
Accounts payable	1,810	(359)	819
Accrued expenses	2,450	552	175
Net cash used in operating activities	(34,603)	(20,369)	(7,636)
Cash flows from investing activities:			
Purchases of property and equipment	(232)	(507)	(417)
Purchases of marketable securities	(148,764)	(82,513)	(5,035)
Proceeds from sales and maturities of marketable securities	87,093	6,069	3,673
Net cash used in investing activities	(61,903)	(76,951)	(1,779)
Cash flows from financing activities:			
Proceeds from issuance of common stock in connection with private placement, net of issuance costs	18,547	—	—
Proceeds from follow-on public offering, net of issuance costs	98,158	—	—
Proceeds from initial public offering, net of issuance costs	—	56,550	—
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	39,864	10,584
Proceeds from the exercise of employee stock options	121	—	—
Net cash provided by financing activities	116,826	96,414	10,584
Net increase (decrease) in cash and cash equivalents	20,320	(906)	1,169
Cash and cash equivalents at beginning of period	9,851	10,757	9,588
Cash and cash equivalents at end of period	$ 30,171	$ 9,851	$ 10,757
Supplemental disclosure of non-cash investing and financing activities:			
Additions to property and equipment included in accounts payable	$ 11	$ 2	$ 91
Fair value of stock issued in connection with Vixen acquisition	$ 2,355	$ —	$ —
Offering costs included in accounts payable	$ 250	$ —	$ —
Accretion of convertible preferred stock to redemption value	$ —	$ 1,764	$ 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 consolidated financial statements.

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ACLARIS THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Amounts in thousands, except share and per share data)

1. Organization and Nature of Business

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. On July 17, 2015, Aclaris Therapeutics International Limited ("ATIL") was established under the laws of the United Kingdom as a wholly-owned subsidiary of Aclaris Therapeutics, Inc. On March 24, 2016, Vixen Pharmaceuticals, Inc. ("Vixen") became a wholly-owned subsidiary of Aclaris Therapeutics, Inc. (see Note 12). Aclaris Therapeutics, Inc., together with ATIL and Vixen, are referred to collectively as the "Company". The Company is a clinical stage biotechnology company focused on identifying, developing and commercializing innovative and differentiated drugs to address significant unmet needs in dermatology. The Company's lead drug candidate, A-101 40% Topical Solution, is a proprietary high concentration formulation of 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 Phase 3 clinical trials of A-101 40% Topical Solution in patients with SK, and submitted a New Drug Application ("NDA") to the U.S. Food and Drug Administration ("FDA") in February 2017.

Initial Public Offering

On October 6, 2015, the Company's registration statement on Form S-1 relating to its initial public offering of its common stock (the "IPO") was declared effective by the Securities and Exchange Commission ("SEC"). The Company's common stock began trading on the NASDAQ Global Select Market on October 7, 2015. The IPO closed on October 13, 2015, and 5,000,000 shares of common stock were sold at a price to the public of $11.00 per share, for aggregate gross proceeds of $55,000. In addition, upon the closing of the IPO, all of the Company's outstanding convertible preferred stock was converted into an aggregate total of 11,677,076 shares of common stock. The conversion of the convertible preferred stock was a non-cash transaction which has been excluded from the Consolidated Statements of Cash Flows.

On October 12, 2015, the underwriters of the IPO exercised in full their option to purchase additional shares, and on October 13, 2015, the Company sold 750,000 additional shares of common stock at a price to the public of $11.00 per share, for aggregate gross proceeds of $8,250.

The Company paid underwriting discounts and commissions of $4,428 to the underwriters in connection with the IPO, including the underwriters' exercise of their option to purchase additional shares. In addition, the Company incurred expenses of $2,272 in connection with the IPO. The net offering proceeds received by the Company, after deducting underwriting discounts, commissions and offering expenses, were $56,550.

Private Placement

On June 2, 2016, pursuant to a securities purchase agreement with certain accredited investors dated May 27, 2016, the Company closed a private placement in which it sold an aggregate of 1,081,082 shares of common stock at a price of $18.50 per share, for gross proceeds of $20,000. The Company incurred placement agent fees of $1,300 and expenses of $153 in connection with the private placement. The net offering proceeds received by the Company, after deducting placement agent fees and transaction expenses, were $18,547.

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Follow-On Offering

On November 13, 2016, the Company's registration statement on Form S-3 was declared effective by the SEC. On November 17, 2016, the Company entered into an underwriting agreement with representatives of the underwriters, to issue and sell 4,000,000 shares of common stock pursuant to the registration statement filed on Form S-3 (the "Follow-On Offering"). The shares of common stock were sold to the public at a price of $22.75 per share, for gross proceeds of $91,000. On November 17, 2016, the underwriters of the Follow-On Offering exercised in full their option to purchase 600,000 additional shares of common stock at a price to the public of $22.75 per share, for gross proceeds of $13,650.

The Company paid underwriting discounts and commissions of $6,279 to the underwriters in connection with the Follow-On Offering, including the underwriters' exercise of their option to purchase additional shares. In addition, the Company incurred expenses of $188 in connection with the Follow-On Offering. The net offering proceeds received by the Company, after deducting underwriting discounts, commissions and offering expenses, were $98,158.

Liquidity

The Company's consolidated 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. At December 31, 2016, the Company had cash, cash equivalents and marketable securities of $174,134 and an accumulated deficit of $90,912. The Company has not generated any product revenues and has not achieved profitable operations. There is no assurance that profitable operations will ever be achieved, and, if achieved, will be sustained on a continuing basis. In addition, development activities, clinical and pre-clinical testing, and commercialization of the Company's drug candidates will require significant additional financing. The Company expects that its cash, cash equivalents and marketable securities as of December 31, 2016, will be sufficient to fund its operations for a period greater than 12 months from the date of issuance of these consolidated financial statements based on its current operating assumptions. 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The financial statements include the consolidated accounts of the Company and its wholly-owned subsidiaries, ATIL and Vixen. All intercompany transactions have been eliminated.

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, research and development expenses and the valuation of stock-based awards.

Estimates are periodically reviewed in light of changes in circumstances, facts and experience. Actual results could differ from the Company's estimates.

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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 licensing agreements, fees paid under a third party assignment agreement and other operational costs related to the Company's research and development activities, including depreciation expenses and the cost of research and development contracts which the Company has entered into with outside vendors to conduct both preclinical studies and clinical trials. Significant judgment and estimates are made in determining the amount of research and development costs recognized in each reporting period. The Company analyzes the progress of its preclinical studies and clinical trials, completion of milestone events, invoices received and contracted costs when estimating research and development costs. Actual results could differ from the Company's estimates. The Company's historical estimates for research and development costs have not been materially different from the actual costs.

Foreign Currency Translation

The reporting currency of the Company is the U.S. Dollar. The functional currency of ATIL, the Company's wholly-owned subsidiary, is the British Pound. Assets and liabilities of ATIL are translated into U.S. Dollars based on exchange rates at the end of each reporting period. Revenues and expenses are translated at average exchange rates during the reporting period. Gains and losses arising from the translation of assets and liabilities are included as a component of accumulated other comprehensive loss within the Company's consolidated balance sheet. Gains and losses resulting from foreign currency transactions are reflected within the Company's consolidated statements of operations. The Company has not utilized foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

Stock-Based Compensation

The Company measures the compensation expense of stock-based awards granted to employees and directors using the grant date fair value of the award. The Company has issued stock options and restricted stock unit ("RSU") awards with service-based vesting conditions, as well as with performance-based vesting conditions. The Company has not issued awards that include market-based conditions. For service-based awards the Company recognizes stock-based compensation expense on a straight-line basis over the requisite service period. For performance-based awards the Company recognizes stock-based compensation expense on a straight-line basis over the requisite service period beginning in the period that it becomes probable the performance conditions will occur. At each balance sheet date, the Company evaluates whether any performance conditions related to a performance-based award have changed. The effect of any change in performance conditions would be recognized as a cumulative catch-up adjustment in the period such change occurs, and any remaining unrecognized compensation expense would be recognized on a straight-line basis over the remaining requisite service period. The impact of forfeitures is recognized in the period in which they occur.

The Company initially measures the compensation expense of stock-based awards granted to consultants using the grant date fair value of the award. Compensation expense is recognized over the period during which services are rendered by such consultants. At the end of each financial reporting period prior to completion of services being rendered, the compensation expense related to these awards is remeasured using the then current fair value of the Company's common stock for RSUs, or based upon updated assumptions in the Black-Scholes option pricing model for stock option awards.

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.

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The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company estimates its expected stock volatility based on the historical volatility of a set of peer companies, which are publicly traded, and expects to continue to do so until it has adequate historical data regarding the volatility of its own publicly-traded stock price. The expected term of the Company's stock options has been determined using 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. The Company uses an expected dividend yield of zero based on the fact that the Company has never paid cash dividends and does not expect to pay cash dividends in the future. Prior to the IPO, the Company valued its common stock using a hybrid method to estimate its enterprise value. The hybrid method used was a probability-weighted expected return method which was a scenario-based methodology that estimated the fair value of the Company's common stock based upon an analysis of future values for the Company assuming various outcomes. The hybrid method used calculated equity values using an option pricing model in one or more of scenarios, and also considered the rights of each class of stock.

The fair value of each RSU is measured using the closing price 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.

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 consolidated 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 consolidated 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.

Reverse Stock Split

On September 24, 2015, the Company effected a 1 for 3.45 reverse stock split of its issued and outstanding shares of common stock and a proportional adjustment to the existing conversion ratios for each series of the Company's then-outstanding convertible preferred stock. Accordingly, all share and per share amounts for all periods presented in these consolidated financial statements and notes thereto have been adjusted retroactively, where applicable, to reflect this reverse stock split and adjustment of the preferred stock conversion ratios.

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Accretion of Convertible Preferred Stock

Accretion of convertible preferred stock included the accretion of accruing dividends on and issuance costs of the Company's Series A, B and C convertible preferred stock. The carrying values of the Series A and Series B convertible preferred stock were accreted to their respective redemption values, using the effective interest method, from the date of issuance through August 28, 2015. In connection with the closing of the Company's Series C convertible preferred stock financing on August 28, 2015, the redemption rights of the Series A and B convertible preferred stock were removed. Subsequent to August 28, 2015, the Company was no longer required to record the accumulated undeclared dividends on its balance sheet, but was thereafter required to deduct accumulated undeclared dividends as part of its earnings per share calculation. On October 13, 2015, in connection with the Company's IPO, all of the Company's convertible preferred stock was converted to common stock.

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, foreign currency translation adjustments 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, plus the weighted average number of potential shares of common stock from the assumed exercise of stock options, and the assumed vesting of RSUs and restricted stock granted by the Company upon its formation, if dilutive. Prior to the IPO, the Company applied the two-class method of calculating its basic and diluted net loss per share attributable to common stockholders since its convertible preferred stock and common stock were participating securities. The Company's convertible preferred stock contractually entitled the holders of such shares to participate in dividends, but not in losses, of the Company. Since the Company was in a net loss position, and preferred stockholders did not participate in losses, basic and diluted net loss per share was the same for each of the periods presented.

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 have consisted of money market accounts,

commercial paper and corporate debt securities with original maturities of less than three months, 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, if any, are included in other income, net within the consolidated 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.

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Assets Held for Sale

In order for an asset to be classified as held for sale, several criteria must be achieved. These criteria include, among others, an active program to market an asset and locate a buyer, as well as the probable disposition of the asset within one year. Upon being classified as held for sale, the recoverability of the carrying value of an asset must be assessed and evaluated. After the valuation process is completed, the held for sale asset is reported at the lower of its carrying value or fair value less cost to sell, and no additional depreciation expense is recognized related to the asset. Once an asset is classified as held for sale, all of its historical balance sheet information is included in prepaid expenses and other current assets in the accompanying consolidated balance sheets. During the year ended December 31, 2015, the Company determined that several pieces of machinery used in the Company's scale-up operations would no longer be part of the Company's future operations. The Company engaged a third-party to market the assets and locate a buyer in the fourth quarter of 2015. During the year ended December 31, 2016, the Company was unable to locate a buyer for the machinery and, therefore, wrote the remaining value of the machinery down to zero. The Company recorded impairment charges of $216 and $289 in the years ended December 31, 2016 and 2015, respectively. The impairment charges are included in research and development expense on the Company's consolidated statement of operations and comprehensive loss. As of December 31, 2016 and 2015, $0 and $216 in assets were classified as held for sale, respectively.

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.

- 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 value of the Company’s accounts payable and accrued expenses approximate fair value 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.

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Deferred Offering Costs

The Company recorded legal, accounting and other third-party fees associated directly with the filing of its registration statement on Form S-3 in November 2016, as deferred offering costs (non-current). These deferred offering costs are recorded in stockholders' equity as a reduction of the proceeds generated from offerings consummated under the Form S-3 on a pro rata basis. The Company may also record legal, accounting and other third-party fees directly associated with in-process equity financings as deferred offering costs (non-current) until such financings are completed. The deferred costs related to an in-process equity financing are recorded in stockholders' equity as a reduction of the proceeds generated from the related offering when it is completed. Deferred offering costs of $116 and $0 were recorded as of December 31, 2016 and 2015, respectively.

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. Furniture and fixtures are depreciated over five years. Leasehold improvements are depreciated over the shorter of the lease term or their useful life. 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 asset over its fair value, determined based on discounted cash flows.

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 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 January 2017, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2017-01, Business Combinations-Clarifying the Definition of a Business (Topic 805). The amendments in this ASU provide a screen to determine when a set of acquired assets and/or activities is not a business. The screen requires that when substantially all of the fair value of the gross assets acquired, or disposed of, is concentrated in a single identifiable asset or a group of similar identifiable assets, the set is not a business. The amendments in this ASU will reduce the number of transactions that meet the definition of a business. ASU 2017-01 is effective for annual reporting periods beginning after December 15, 2017, including interim periods within those years, and early adoption will be permitted. The Company is assessing the potential impact of ASU 2017-01 on its consolidated financial statements.

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In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326). This ASU introduces a new model for recognizing credit losses on financial instruments based upon estimated expected credit losses. ASU 2016-13 will apply to loans, accounts receivable, financial assets measured at amortized cost and at fair value through other comprehensive income, loan commitments and certain off-balance sheet credit exposures. ASU 2016-13 is effective for annual reporting periods beginning after December 15, 2019, including interim periods within those years, and early adoption will be permitted. The Company is assessing the potential impact of ASU 2016-13 on its consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, Improvements to Employee Share-Based Payment Accounting. This ASU requires all tax effects of share-based payment settlements to be recorded through the income statement. Currently, tax benefits in excess of compensation cost, or “windfalls”, are recorded in equity, and tax deficiencies, or “shortfalls”, are recorded to equity to the extent of previous windfalls, and then to the income statement. In addition, under the new guidance, companies will be permitted to make a policy election to recognize the impact of forfeitures either when they occur, or on an estimated basis. Finally, this update simplifies withholding requirements to allow companies to withhold up to an employee’s maximum tax rate without resulting in liability classification for the award. ASU 2016-09 is effective for annual reporting periods beginning after December 15, 2016, and early adoption is permitted. The Company has adopted the provisions of this standard early, the impact of which on its consolidated financial statements was not significant.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). The new standard establishes a right-of-use (“ROU”) model that requires a lessee to record a ROU asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. A modified retrospective transition approach is required for lessees for capital and operating leases existing at, or entered into after, the beginning of the earliest comparative period presented in the financial statements, with certain practical expedients available. The Company is currently evaluating the potential impact of the adoption of this standard.

In January 2016, the FASB issued ASU 2016-01, Recognition and Measurement of Financial Assets and Financial Liabilities. The amendments in this update revise the accounting related to the classification and measurement of investments in equity securities and the presentation of certain fair value changes for financial liabilities measured at fair value. The amendments are effective for annual reporting periods beginning after December 15, 2017, including interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the potential impact of the adoption of this standard.

In November 2015, the FASB issued ASU 2015- 17, Balance Sheet Classification of Deferred Taxes. The amendments in this update simplify the presentation of deferred income taxes to require that deferred tax liabilities and assets are classified as noncurrent in a statement of financial position. The amendments are effective for annual reporting periods beginning after December 15, 2016 and interim reporting periods within those annual periods. Early

application is permitted. The Company has adopted the provisions of this standard early, the impact of which on its consolidated financial statements was not significant.

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3. Fair Value of Financial Assets and Liabilities

The following tables present information about the fair value measurements of the Company's financial assets and liabilities which are measured at fair value on a recurring basis, and indicate the level of the fair value hierarchy utilized to determine such fair values:

	December 31, 2016			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 11,522	$ 12,691	$ —	$ 24,213
Marketable securities	—	143,963	—	143,963
Total	$ 11,522	$ 156,654	$ —	$ 168,176

	December 31, 2015			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 8,810	$ 250	$ —	$ 9,060
Marketable securities	—	82,187	—	82,187
Total	$ 8,810	$ 82,437	$ —	$ 91,247

As of December 31, 2016 and 2015, the Company's cash equivalents consisted of investments with maturities of less than three months and included a money market fund which was valued based upon Level 1 inputs, and commercial paper and corporate debt securities which were valued based upon Level 2 inputs. In determining the fair value of its Level 2 investments the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third party pricing service based on available trade, bid and other observable market data for identical securities. Quarterly, the Company compares the quoted prices obtained from the third party pricing service to other available independent pricing information to validate the reasonableness of the quoted prices provided. The Company evaluates whether adjustments to third-party pricing is necessary and, historically, the Company has not made adjustments to quoted prices obtained from the third-party pricing service third party pricing are necessary. During the years ended December 31, 2016 and 2015, there were no transfers between Level 1, Level 2 and Level 3.

As of December 31, 2016 and 2015, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

	December 31, 2016			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 51,352	$ —	$ (59)	$ 51,293
Commercial paper	20,463	—	—	20,463
Asset-backed securities	28,692	6	(1)	28,697
U.S. government agency debt securities	43,505	8	(3)	43,510
Total marketable securities	$ 144,012	$ 14	$ (63)	$ 143,963

	December 31, 2015			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 46,270	$ —	$ (125)	$ 46,145
Commercial paper	9,789	—	—	9,789
Asset-backed securities	6,234	—	(14)	6,220
U.S. government agency debt securities	20,048	—	(15)	20,033
Total marketable securities	$ 82,341	$ —	$ (154)	$ 82,187

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4. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2016	2015
Computer equipment	$ 310	$ 262
Manufacturing equipment	149	101
Furniture and fixtures	115	39
Leasehold improvements	33	—
Property and equipment, gross	607	402
Accumulated depreciation	(126)	(42)
Property and equipment, net	$ 481	$ 360

Depreciation expense was $120, $90 and $12 for the years ended December 31, 2016, 2015 and 2014, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2016	2015
Research and development expenses	$ 1,166	$ 123
Employee compensation expenses	1,732	—
Licensing fees	—	250
Vixen contract payable	100	—
Professional fees	77	283
Other	303	89
Total accrued expenses	$ 3,378	$ 745

6. Stockholders’ Equity

Preferred Stock

As of December 31, 2016 and 2015, the Company's amended and restated certificate of incorporation authorized the Company to issue 10,000,000 shares of undesignated preferred stock. There were no shares of preferred stock outstanding as of December 31, 2016 and 2015.

The Company previously issued Series A, Series B and Series C convertible preferred stock (collectively, the "Preferred Stock"). Through August 28, 2015, the Company had issued an aggregate of 11,677,076 shares of Preferred Stock in the Series A, Series B and Series C offerings. Upon the closing of the Company's IPO in October 2015, all of the then outstanding Preferred Stock was converted into an aggregate total of 11,677,076 shares of common stock. Also in connection with the IPO, the Company amended and restated its certificate of incorporation and authorized 10,000,000 shares of undesignated preferred stock.

Common Stock

As of December 31, 2016 and 2015, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 100,000,000 shares 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 any preferential dividend rights of any series of preferred stock that may be outstanding. No dividends had been declared through December 31, 2016.

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Restricted Common Stock

In July 2012, the Company issued 2,730,427 shares of restricted common stock with time-based vesting to its founders in connection with the formation of the Company. Unvested shares of restricted common stock could not be sold or transferred by the holders of those shares. Of the shares issued in July 2012, 1,918,834 shares were subject to vesting pursuant to restricted stock agreements with 25% vesting in July 2013 and the remaining 75% vesting in equal monthly installments over a three-year period thereafter. Upon the Company's IPO in October 2015, all remaining unvested shares of restricted common stock vested immediately. The estimated grant date fair value of the restricted common stock issued was $0.00001 per share, equal to the par value of each share issued. The aggregate fair value of restricted common stock that vested during the years ended December 31, 2016, 2015 and 2014 was $0, $6,423 and $448, respectively. As of December 31, 2016 and 2015, no shares were subject to repurchase.

7. Stock Based Awards

2015 Equity Incentive Plan

On September 15, 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (the "2015 Plan"), and on September 16, 2015, the Company's stockholders approved the 2015 Plan. The 2015 Plan became effective in connection with the Company's IPO in October 2015. At the time the 2015 Plan became effective, no further grants may be made under the Company's 2012 Equity Compensation Plan, as amended and restated (the "2012 Plan"). The 2015 Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, RSUs, performance stock awards, cash based awards and other stock-based awards. The number of shares initially reserved for the issuance of awards under the 2015 Plan was 1,643,872. The number of shares of common stock that may be issued under the 2015 Plan will automatically increase on January 1 of each year, beginning on January 1, 2016 and ending on January 1, 2025, in an amount equal to the lesser of (i) 4.0% of the shares of the Company's common stock outstanding on December 31 of the preceding calendar year or (ii) an amount determined by the Company's board of directors. The shares of common stock underlying any awards that expire, are otherwise terminated, settled in cash or repurchased by the Company under the 2015 Plan and the 2012 Plan will be added back to the shares of common stock available for issuance under the 2015 Plan. As of December 31, 2016, 607,556 shares remained available for grant under the 2015 Plan. As of January 1, 2017, the number of shares of common stock available for issuance under the 2015 Plan was automatically increased by 1,042,367 shares. The 2015 Plan is administered by the Company's 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, 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 has granted stock based awards that vest subject to the satisfaction of a service requirement ("service based awards"), as well as awards that vest subject to the satisfaction of specific performance-based conditions ("performance-based awards").

2012 Equity Compensation Plan

Upon the 2015 Plan becoming effective, no further grants can be made under the 2012 Plan. The Company granted a total of 1,140,524 stock options under the 2012 Plan, of which 1,049,667 and 1,140,524 were outstanding as of December 31, 2016, and 2015, respectively. Stock options granted under the 2012 Plan vest over four years and expire after ten years. As required, the exercise price for the stock options granted under the 2012 Plan was not less than the fair value of common shares as determined by the Company as of the date of grant.

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Stock Option Valuation

The weighted average assumptions the Company used to estimate the fair value of stock options granted during the years ended December 31, 2016, 2015 and 2014 were as follows:

	Year Ended December 31,		
	2016	2015	2014
Risk-free interest rate	2.06 %	1.78 %	1.87 %
Expected term (in years)	6.5	6.3	6.4
Expected volatility	94.86 %	93.90 %	113.90 %
Expected dividend yield	0 %	0 %	0 %

The Company recognizes compensation expense for awards over their vesting period. Compensation expense for awards includes the impact of forfeiture in the period when they occur.

Stock Options

The following table summarizes stock option activity for the years ended December 31, 2016, 2015 and 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	500,262	$ 1.22		
Exercised	—	—		
Forfeited and canceled	—	—		
Outstanding as of December 31, 2014	500,262	1.22	9.77	$ 305
Granted	1,238,262	18.08		
Exercised	—	—		
Forfeited and canceled	—	—		
Outstanding as of December 31, 2015	1,738,524	13.23	9.51	24,722
Granted	1,083,919	27.12		

Exercised	(51,980)	2.37		
Forfeited and canceled	(68,113)	15.71		
Outstanding as of December 31, 2016	2,702,350	$ 18.94	9.05	$ 24,434
Options vested and expected to vest as of December 31, 2016	2,702,350	$ 18.94	9.05	$ 24,434
Options exercisable as of December 31, 2016	575,149 (1)	$ 10.93	8.42	$ 9,512

(1) All options granted 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, 2016.

The weighted average grant date fair value of stock options granted during the years ended December 31, 2016, 2015 and 2014 was $21.16, $13.84 and $1.38 per share, respectively.

The intrinsic value of a stock option is calculated as the difference between the exercise price of the stock option and the fair value of the underlying common stock, and cannot be less than zero.

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Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2016 and 2015. The Company did not grant RSUs during the year ended December 31, 2014.

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2014	—	—
Granted	53,800	$ 28.68
Vested	—	
Forfeited and cancelled	—	
Outstanding as of December 31, 2015	53,800	28.68
Granted	180,764	27.16
Vested	(12,950)	28.68
Forfeited and cancelled	(2,000)	28.68
Outstanding as of December 31, 2016	219,614	$ 27.43

Stock Based Compensation

The following table summarizes stock-based compensation expense recorded by the Company for the years ended December 31, 2016, 2015 and 2014:

	Year Ended December 31,		
	2016	2015	2014
Research and development	$ 2,291	$ 257	$ 10
General and administrative	3,813	634	17
	$ 6,104	$ 891	$ 27

As of December 31, 2016, the Company had unrecognized stock based compensation expense for stock options and RSUs of $34,349 and $5,790, respectively, which is expected to be recognized over weighted average periods of 3.49 years and 2.83 years, respectively.

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8. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders was calculated as follows:

	Year Ended December 31, 2016	2015	2014
Numerator:			
Net loss	$ (48,079)	$ (20,563)	$ (8,517)
Accretion of redeemable convertible preferred stock	—	(2,566)	(2,054)
Net loss attributable to common stockholders	$ (48,079)	$ (23,129)	$ (10,571)
Denominator:			
Weighted average shares of common stock outstanding	21,415,733	6,637,678	2,730,427
Less: Weighted average shares of unvested restricted common stock outstanding	—	(530,636)	(1,010,345)
Weighted average common shares outstanding used in calculating net loss per share attributable to common stockholders, basic and diluted	21,415,733	6,107,042	1,720,082
Net loss per share attributable to common stockholders, basic and diluted	$ (2.25)	$ (3.79)	$ (6.15)

To calculate net loss attributable to common stockholders the Company reduced the net loss for the accretion of issuance costs and cumulative dividends accrued but not paid through August 28, 2015, and the remaining cumulative dividends accrued but not paid through October 13, 2015, the date on which all convertible preferred stock converted to common stock.

The Company’s potential dilutive securities, which included stock options, RSUs, preferred stock, and shares of restricted common stock that were issued but not yet vested, have been excluded from the computation of diluted net loss per share since 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 table presents potential common shares excluded from the calculation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2016, 2015 and 2014. All share amounts presented in the table below represent the total number outstanding as of December 31.

	2016	2015	2014
Stock options to purchase common stock	2,702,350	1,738,524	500,262
Restricted stock unit awards	219,614	53,800	—

Unvested restricted common stock	—	—	759,538
Convertible preferred stock (as converted to common stock)	—	—	7,924,919
	2,921,964	1,792,324	9,184,719

9. Commitments and Contingencies

Agreements for Office Space

In August 2013, the Company entered into a sublease agreement for its office space with related parties (see Note 11), with a term ending on November 30, 2016. As part of an amendment to the sublease agreement entered into in December 2014, the Company increased the amount of office space to be subleased and agreed to new monthly sublease terms commencing in January 2015. On August 14, 2015, the Company further amended its sublease agreement to increase the square footage of the space and to extend the term of the sublease to November 2019. Effective December 1, 2015, the Company further amended its sublease agreement to increase the square footage and agreed to new monthly sublease terms.

In November 2016, the Company entered into a lease agreement with a third-party for additional office space in the same building as its headquarters with a term beginning in February 2017, and ending in November 2019.

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Rent expense was $254, $119 and $66 for the years ended December 31, 2016, 2015 and 2014, respectively. The Company recognizes rent expense on a straight-line basis over the term of the agreement and has accrued for rent expense incurred but not yet paid.

As of December 31, 2016, future minimum lease payments under the sublease were as follows:

Year Ending December 31,	
2017	$ 350
2018	363
2019	339
2020	—
2021	—
Total	$ 1,052

Stock Purchase Agreement with Vixen Pharmaceuticals, Inc

Pursuant to the stock purchase agreement with Vixen the Company is obligated to make annual payments of $100 on March 24th of each year, through March 24, 2022, with such amounts being creditable against specified future payments.

License and Collaboration Agreement with JAKPharm LLC and Key Organics, LTD

Pursuant to a commercial license agreement with JAKPharm LLC (“JAKPharm”) and Key Organics, LTD (“Key Organics” and collectively, “Licensors”) for the development and commercialization of products containing specified compounds developed by the Licensors, the Company is obligated to make annual maintenance payments of $50 per year, which will be creditable against any payments made in such calendar year.

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 consolidated financial statements as of December 31, 2016 or 2015.

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 used to dispense A-101 40% Topical Solution in Phase 3 clinical trials, and intends to use for the commercial drug product. The agreement has 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 40% Topical Solution, 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 40% Topical Solution, 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 40% Topical Solution.

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10. Income Taxes

During the years ended December 31, 2016, 2015 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.

Loss before income taxes is allocated as follows:

	Year Ended December 31,		
	2016	2015	2014
U.S. operations	$ (40,597)	$ (11,823)	$ (8,517)
Foreign operations	(7,482)	(8,740)	—
Loss before income taxes	$ (48,079)	$ (20,563)	$ (8,517)

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,		
	2016	2015	2014
Federal statutory income tax rate	(34.0)%	(34.0)%	(34.0)%
State taxes, net of federal benefit	(5.2)	(3.8)	(6.6)
Foreign rate differential	3.2	6.0	—
Permanent differences	1.8	—	—
Research and development tax credits	(2.0)	(1.5)	(1.0)
Change in deferred tax asset valuation allowance	36.2	33.3	41.6
Effective income tax rate	— %	— %	— %

Net deferred tax assets as of December 31, 2016 and 2015 consisted of the following:

	December 31,	
	2016	2015
Deferred tax assets:		
Net operating loss carryforwards	$ 16,836	$ 5,750
Capitalized start up costs	8,840	4,401
Research and development tax credit carryforwards	1,480	500
Capitalized research and development expenses	594	611

Intangible asset	1,403	1,650
Stock based compensation expenses	2,629	373
Property and equipment	199	—
Other	2	1
Total deferred tax assets	31,983	13,286
Deferred tax liabilities:		
Section 481(a) adjustment	(1,257)	—
Other	—	—
Total deferred tax liabilities	(1,257)	—
Valuation allowance	(30,726)	(13,286)
Net deferred tax assets	$ —	$ —

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As of December 31, 2016, the Company had federal and state net operating loss carryforwards of $38,137 for each, which begin to expire in 2032. As of December 31, 2016, the Company also had federal and state research and development tax credit carryforwards of $1,488, which begin to expire in 2032. The Company also has $7,972 of loss carry forwards in the United Kingdom, which can be carried forward indefinitely. Utilization of the net operating loss carryforwards and research and development tax credit carryforwards in the United States may be subject to a substantial annual limitation under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that may 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 stockholders 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, 2016 and 2015. 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, 2016, 2015, and 2014 related primarily to the increases in net operating loss carryforwards, capitalized start-up costs, and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,		
	2016	2015	2014
Valuation allowance at beginning of year	$ (13,286)	$ (6,444)	$ (2,899)
Decreases recorded as benefit to income tax provision	—	—	—
Increases recorded to income tax provision	(17,440)	(6,842)	(3,545)
Valuation allowance as of end of year	$ (30,726)	$ (13,286)	$ (6,444)

During the year ended December 31, 2015, the Company recorded unrecognized tax benefits in the amount of $4,440 related to start-up costs that were previously deducted beginning in the initial return filing period ended December 31, 2012. During the year ended December 31, 2016, the Company filed a method of accounting change with the IRS

related to the start-up costs, and reversed the related unrecognized tax position. The following table summarizes the changes in the Company's unrecognized tax benefits:

	Year ended December 31,		
	2016	2015	2014
Unrecognized tax benefits at beginning of year	$ (4,400)	$ —	$ —
Increases related to prior year tax provisions		(2,624)	—
Decreases related to prior year tax provisions	4,400	—	—
Increases related to current year tax provisions		(1,776)	—
Unrecognized tax benefits as of end of year	$ —	$ (4,400)	$ —

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The total amount of unrecognized tax benefits that, if recognized, would impact the Company's effective tax rate were $0 as of both December 31, 2016 and 2015. The Company accrues interest and penalties related to unrecognized tax benefits in income tax expense in the consolidated statements of operations and comprehensive loss. During each of the years ended December 31, 2016, 2015 and 2014, the Company recognized expense/(benefit) of $0 related to interest and penalties.

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.

11. Related Party Transactions

In August 2013, the Company entered into a sublease agreement with NeXeption, Inc. ("NeXeption"), which was subsequently amended in December 2014, August 2015 and October 2016. In August 2015, pursuant to an Assignment and Assumption Agreement, NeXeption assigned all interests, rights, duties and obligations under the sublease to NST Consulting, LLC, a wholly-owned subsidiary of NST, LLC. Mr. Stephen Tullman, the chairman of the Company's board of directors, was an executive officer of NeXeption and is also the manager of NST Consulting, LLC and NST, LLC. Total payments made under the sublease during the years ended December 31, 2016, 2015 and 2014, were $387, $124 and $66, respectively.

In February 2014, the Company entered into a services agreement with NST, LLC (the "NST Services Agreement"), pursuant to which NST, LLC provided certain pharmaceutical development, management and other administrative services to the Company. Under the same agreement, the Company also provided services to another company under common control with the Company and NST, LLC and was reimbursed by NST, LLC for those services. In addition to Mr. Tullman's role as manager of NST, LLC, several of the Company's executive officers are members of 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. Under the NST Services Agreement, as amended, NST Consulting, LLC provides services to the Company and the Company provides services to another company under common control with the Company and NST Consulting, LLC. The NST Services Agreement was further amended in August 2015, November 2015 and December 2016 to adjust the amount of services the Company is obligated to provide to NST Consulting, LLC and the amount of services NST Consulting, LLC is obligated to provide to the Company. The Company may offset any payments owed by the Company to NST

Consulting, LLC against payments that are owed by NST Consulting, LLC to the Company for the provision of personnel, including consultants, to the Company.

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During the years ended December 31, 2016, 2015 and 2014 amounts included in the consolidated statement of operations for the NST Services Agreement are summarized in the following table:

	Year Ended December 31,		
	2016	2015	2014
Services provided by NST Consulting, LLC	$ 323	$ 455	$ 467
Services provided to NST Consulting, LLC	(56)	(294)	(158)
General and administrative expense, net	$ 267	$ 161	$ 309
Services provided by NST Consulting, LLC	$ 246	$ 52	$ —
Services provided to NST Consulting, LLC	(97)	(259)	(255)
Research and development expense, net	$ 149	$ (207)	$ (255)
Services provided by NST Consulting, LLC	$ 569	$ 507	$ 467
Services provided to NST Consulting, LLC	(153)	(553)	(413)
Total, net	$ 416	$ (46)	$ 54
Net payments made to (received from) NST	$ 325	$ (46)	$ 54

The Company had $91 and $0 payable to NST Consulting, LLC under the NST Services Agreement as of December 31, 2016, and December 31, 2015, respectively.

12. Agreements Related to Intellectual Property

Assignment Agreement and Finder’s Services Agreement

In August 2012, the Company entered into an assignment agreement with the Estate of Mickey Miller (the “Miller Estate”) under which the Company 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, the Company has the sole and exclusive right, but not the duty, to develop, obtain regulatory approval for and commercialize A-101 in various countries throughout the world. The Company is 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, the Company 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, the Company made one-time milestone payments of $400 in 2013 upon the dosing of the first human subject with A-101 40% Topical Solution in the Company's Phase 2 clinical trial. There are no remaining potential milestone payments under the assignment agreement. Under the finder's services agreement, the Company made a one-time milestone payment of $300 in the year ended December 31, 2016 upon the dosing of the first human subject with A-101 40% Topical Solution in the Company's Phase 3 clinical trial and is obligated to make additional milestone payments of up to $1,000 in the aggregate upon the achievement of specified development and regulatory milestones and up to $4,500 upon the achievement of specified commercial milestones. The Company recorded the $300 milestone payment as general and administrative expense in the year ended December 31, 2016. Under each of the assignment agreement and the finder's services agreement, the Company is 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. The Company has 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.

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License Agreement with Rigel Pharmaceuticals, Inc.

In August 2015, the Company entered into an exclusive, worldwide license and collaboration agreement with Rigel Pharmaceuticals, Inc. (“Rigel”) for the development and commercialization of products containing specified JAK inhibitors developed by Rigel. Under this agreement, the Company intends to develop these JAK inhibitors for the treatment of alopecia areata and potentially for other dermatological conditions. During the year ended December 31, 2015, the Company made an upfront non-refundable payment of $8,000 to Rigel. In addition, the Company has agreed to make aggregate payments of up to $80,000 upon the achievement of specified pre commercialization milestones, such as clinical trials and regulatory approvals. Further, the Company has agreed to pay up to an additional $10,000 to Rigel upon the achievement of a second set of development milestones. With respect to any products the Company commercializes under the agreement, the Company will pay Rigel quarterly tiered royalties on its annual net sales of each product at a high single digit percentage of annual net sales, subject to specified reductions, until the date that all of the patent rights for that product have expired, as determined on a country by country and product by product basis or, in specified countries under specified circumstances, ten years from the first commercial sale of such product.

The agreement terminates on the date of expiration of all royalty obligations unless earlier terminated by either party for a material breach. The Company may also terminate the agreement without cause at any time upon advance written notice to Rigel. Rigel, after consultation with the Company, will be responsible for maintaining and prosecuting the patent rights, and the Company will have final decision making authority regarding such patent rights for a product in the United States and the European Union. To the extent that the Company and Rigel jointly develop intellectual property, the parties will confer and decide which party will be responsible for filing, prosecuting and maintaining those patent rights. The agreement also establishes a joint steering committee composed of an equal number of representatives for each party which will monitor progress in the development of products.

The Company accounted for the transaction as an asset acquisition as the licensing arrangement did not meet the definition of a business pursuant to the guidance prescribed in ASC Topic 805, Business Combinations. Accordingly, the Company recorded the $8,000 upfront payment as research and development expense in the year ended December 31, 2015. The Company will record as expense any contingent milestone payments or royalties in the period in which such liabilities are incurred. The Company concluded that licensing arrangement with Rigel did not meet the definition of a business because the transaction principally resulted in its acquisition of intellectual property. As part of the transaction, the Company did not acquire any employees or tangible assets, or any processes, protocols or operating systems. In addition, at the time of the acquisition, there were no activities being conducted related to the licensed patents. The Company will expense the acquired intellectual property asset as of the acquisition date on the basis that costs of intangible assets that are purchased from others for use in research and development activities and that have no alternative future uses are research and development costs at the time the costs are incurred.

License and Collaboration Agreement with JAKPharm LLC and Key Organics, LTD

In November 2015, the Company entered into a commercial license agreement with JAKPharm and Key Organics for the development and commercialization of products containing specified compounds developed by the Licensors. During the year ended December 31, 2015, the Company expensed an upfront non-refundable payment of $250 to the Licensors. The Company will also make annual maintenance payments of $50 per year, which will be creditable against any payments made in such calendar year. In addition, the Company has agreed to make aggregate payments of up to $2,350 upon specified pre commercialization milestones, such as clinical trials and regulatory approvals. With respect to any products the Company commercializes under the agreement, the Company will pay the Licensors royalties on its annual net sales of each product at a low single digit percentage of annual net sales, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and licensed product-by-licensed product basis or, in specified countries under specified circumstances, ten years from the first commercial sale of such product. The Company may terminate the agreement without cause with three months written notice to the Licensors.

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The Company accounted for the transaction as an asset acquisition as the licensing arrangement did not meet the definition of a business pursuant to the guidance prescribed in ASC Topic 805, Business Combinations. Accordingly, the Company recorded the $250 upfront payment as research and development expense in the year ended December 31, 2015. The Company will record as expense any contingent milestone payments or royalties in the period in which such liabilities are incurred. The Company concluded that licensing arrangement with the Licensors did not meet the definition of a business because the transaction principally resulted in its acquisition of intellectual property. As part of the transaction, the Company did not acquire any employees or tangible assets, or any processes, protocols or operating systems. In addition, at the time of the acquisition, there were no activities being conducted related to the licensed patents. The Company will expense the acquired intellectual property asset as of the acquisition date on the basis that costs of intangible assets that are purchased from others for use in research and development activities and that have no alternative future uses are research and development costs at the time the costs are incurred.

Stock Purchase Agreement with Vixen Pharmaceuticals, Inc. and License Agreement with Columbia University

On March 24, 2016, the Company entered into a stock purchase agreement (the “Vixen Agreement”) with Vixen, JAK1, LLC, JAK2, LLC and JAK3, LLC (all together with Vixen, the “Selling Stockholders”) and Shareholder Representative Services LLC, a Colorado limited liability company, solely in its capacity as the representative of the Selling Stockholders. Pursuant to the Vixen Agreement, the Company acquired all shares of Vixen’s capital stock from the Selling Stockholders (the “Vixen Acquisition”). Following the Vixen Acquisition, Vixen became a wholly-owned subsidiary of the Company. Pursuant to the Vixen Agreement, the Company paid $600 upfront and issued an aggregate of 159,420 shares of the Company’s common stock to the Selling Stockholders. The Company is obligated to make annual payments of $100 on March 24th of each year, through March 24, 2022, with such amounts being creditable against specified future payments that may be paid under the Vixen Agreement.

The Company is obligated to make aggregate payments of up to $18,000 to the Selling Stockholders upon the achievement of specified pre-commercialization milestones for three products in the United States, the European Union and Japan, and aggregate payments of up to $22,500 upon the achievement of specified commercial milestones. With respect to any commercialized products covered by the Vixen Agreement, the Company is obligated to pay low single-digit royalties on net sales, subject to specified reductions, limitations and other adjustments, until the date that all of the patent rights for that product have expired, as determined on a country-by-country and product-by-product basis or, in specified circumstances, ten years from the first commercial sale of such product. If the Company sublicenses any of Vixen’s patent rights and know-how acquired pursuant to the Vixen Agreement, the Company will be obligated to pay a portion of any consideration the Company receives from such sublicenses in specified circumstances.

As a result of the transaction with Vixen, the Company became party to the Exclusive License Agreement, by and between Vixen and the Trustees of Columbia University in the City of New York (“Columbia”), dated as of December 31, 2015 (the “License Agreement”). Under the License Agreement, the Company is obligated to pay Columbia an annual license fee of $10, subject to specified adjustments for patent expenses incurred by Columbia and creditable against any royalties that may be paid under the License Agreement. The Company is also obligated to pay up to an aggregate of $11,600 upon the achievement of specified commercial milestones, including specified levels of net sales

of products covered by Columbia patent rights and/or know-how, and royalties at a sub-single-digit percentage of annual net sales of products covered by Columbia patent rights and/or know-how, subject to specified adjustments. If the Company sublicenses any of Columbia's patent rights and know-how acquired pursuant to the License Agreement, it will be obligated to pay Columbia a portion of any consideration received from such sublicenses in specified circumstances. The royalties, as determined on a country-by-country and product-by-product basis, are payable until the date that all of the patent rights for that product have expired, the expiration of any market exclusivity period granted by a regulatory body or, in specified circumstances, ten years from the first commercial sale of such product. The License Agreement terminates on the date of expiration of all royalty obligations thereunder unless earlier terminated by either party for a material breach, subject to a specified cure period. The Company may also terminate the License Agreement without cause at any time upon advance written notice to Columbia.

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The Company accounted for the transaction with Vixen as an asset acquisition as the arrangement did not meet the definition of a business pursuant to the guidance prescribed in ASC Topic 805, Business Combinations. The Company concluded the transaction with Vixen did not meet the definition of a business because the transaction principally resulted in the acquisition of the License Agreement. The Company did not acquire tangible assets, processes, protocols or operating systems. In addition, at the time of the transaction, there were no activities being conducted related to the licensed patents. The Company expensed the acquired intellectual property as of the acquisition date on the basis that the cost of intangible assets purchased from others for use in research and development activities, and that have no alternative future uses, are expensed at the time the costs are incurred. Accordingly, the Company recorded the $600 upfront payment, the fair value of the shares of common stock issued of $2,355, and the present value of the six non-contingent annual payments as research and development expense in the year ended December 31, 2016. Additionally, the Company will record as expense any contingent milestone payments or royalties in the period in which such liabilities are incurred.

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 100% of employee contributions to the 401(k) Plan up to 4% of the employee's earnings, subject to certain limitations. Company contributions under the 401(k) Plan were $176, $99 and $60 for the years ended December 31, 2016, 2015 and 2014, respectively.

14. Quarterly Financial Information (unaudited)

This table summarizes the unaudited consolidated financial results of operations for the quarters ended:

	March 31,	June 30,	September 30,	December 31,
2016 Quarter Ended				
Revenue	$ —	$ —	$ —	$ —
Operating expenses	13,139	12,989	10,812	11,627
Other income, net	100	118	118	152
Net loss	(13,039)	(12,871)	(10,694)	(11,475)
Net loss attributable to common stockholders	$ (13,039)	$ (12,871)	$ (10,694)	$ (11,475)

Net loss per share attributable to common stockholders, basic and diluted	$ (0.65)	$ (0.62)	$ (0.50)	$ (0.49)
2015 Quarter Ended				
Revenue	$ —	$ —	$ —	$ —
Operating expenses	2,629	2,596	10,640	4,802
Other income, net	6	2	7	89
Net loss	(2,623)	(2,594)	(10,632)	(4,714)
Net loss attributable to common stockholders	$ (3,280)	$ (3,270)	$ (11,652)	$ (4,927)
Net loss per share attributable to common stockholders, basic and diluted	$ (1.61)	$ (1.52)	$ (5.12)	$ (0.28)

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision of and with the participation of our management, including our chief executive officer, who is our principal executive officer, and our chief financial officer, who is our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2016, the end of the period covered by this Annual Report. The term "disclosure controls and procedures," as set forth in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the Securities and Exchange Commission, or the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2016, our chief executive officer and chief financial officer concluded that, as of such date, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting identified in connection with the evaluation required by Rule 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the year ended December 31, 2016 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Management’s Report on Internal Control over Financial Reporting and Attestation Report of the Registered Public Accounting Firm

Our management is responsible for establishing and maintaining an adequate system of internal control over financial reporting, as defined in the Exchange Act Rule 13a-15(f). Management conducted an assessment of our internal control over financial reporting based on the framework established in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control—Integrated Framework. Based on the assessment, management concluded that, as of December 31, 2016, our internal control over financial reporting was effective.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting as required by Section 404(c) of the Sarbanes Oxley Act of 2002. Because we qualify as an emerging growth company under the JOBS Act, management's report was not subject to attestation by our independent registered public accounting firm.

Item 9B. Other Information

Not applicable.

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PART III

We will file a definitive Proxy Statement for our 2017 Annual Meeting of Stockholders, or the 2017 Proxy Statement, with the SEC, pursuant to Regulation 14A, not later than 120 days after the end of our fiscal year. Accordingly, certain information required by Part III has been omitted under General Instruction G(3) to Form 10-K. Only those sections of the 2017 Proxy Statement that specifically address the items set forth herein are incorporated by reference.

Item 10. Directors, Executive Officers and Corporate Governance

The information required by Item 10 is hereby incorporated by reference to the sections of the 2017 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors," "Executive Officers" and "Section 16(a) Beneficial Ownership Reporting Compliance."

Item 11. Executive Compensation

The information required by Item 11 is hereby incorporated by reference to the sections of the 2017 Proxy Statement under the captions "Executive Compensation" and "Non-Employee Director Compensation."

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by Item 12 is hereby incorporated by reference to the sections of the 2017 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Securities Authorized for Issuance under Equity Compensation Plans."

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by Item 13 is hereby incorporated by reference to the sections of the 2017 Proxy Statement under the captions "Transactions with Related Persons" and "Independence of the Board of Directors."

Item 14. Principal Accountant Fees and Services

The information required by Item 14 is hereby incorporated by reference to the sections of the 2017 Proxy Statement under the caption "Ratification of Selection of Independent Auditors."

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PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)Exhibits

Exhibit Number	Description of Document
2.1#	Stock Purchase Agreement, by and among the Registrant, Vixen Pharmaceuticals, Inc., JAK1, LLC, JAK2, LLC, JAK3, LLC and Shareholder Representative Services LLC, dated as of March 24, 2016 (incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 13, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 13, 2015).
4.1	Specimen stock certificate evidencing shares of Common Stock (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
10.1#	Clinical and Commercial Supply Agreement, by and between the Registrant and PeroxyChem LLC, dated as of August 6, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015).
10.2#	Services Agreement, by and between the Registrant and NST, LLC, dated as of February 5, 2014, as amended on December 19, 2014 and August 11, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015).
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 (incorporated by reference to Exhibit 10.3 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
10.4#	Finder's Services Agreement, by and between the Registrant and KPT Consulting, LLC, dated as of August 25, 2012 (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015).
10.5	Second Amended and Restated Investors' Rights Agreement, dated as of August 28, 2015, by and among the Registrant and certain of its stockholders (incorporated by reference to Exhibit 10.5 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 4, 2015).
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 and August 14, 2015 (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015).
10.7+	

	Amended and Restated 2012 Equity Compensation Plan (incorporated by reference to Exhibit 10.7 to Amendment No. 1 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 4, 2015)).
10.8+	Form of Stock Option Grant under Amended and Restated 2012 Equity Compensation Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015)).
10.9+	2015 Equity Incentive Plan (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form S-8 (File No. 333-207434), filed with the SEC on October 15, 2015).
10.10+	Form of Stock Option Grant Notice and Stock Option Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
10.11+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.11 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).

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10.12		Form of Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015).
10.13+		Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.13 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
10.14#		License and Collaboration Agreement, by and between Aclaris Therapeutics International Limited and Rigel Pharmaceuticals, Inc., dated as of August 27, 2015 (incorporated by reference to Exhibit 10.14 to Amendment No. 3 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on October 1, 2015)).
10.15+		Amended and Restated Employment Agreement, by and between the Registrant and Neal Walker, dated as of October 5, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on November 18, 2015).
10.16+		Employment Agreement, by and between the Registrant and Stuart Shanler, dated as of October 4, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on November 18, 2015).
10.17+		Employment Agreement, by and between the Registrant and Christopher Powala, dated as of September 17, 2015 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on November 18, 2015).
10.18	#	Exclusive License Agreement, by and between The Trustees of Columbia University in the City of New York and Vixen Pharmaceuticals, Inc., dated as of December 31, 2015 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.19#		Third Amendment to Services Agreement by and between the Registrant and NST Consulting, LLC, dated as of November 24, 2015 (incorporated by reference to Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.20	#	Fourth Amendment to Services Agreement by and between the Registrant and NST Consulting, LLC, dated as of January 8, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.21	#	Fifth Amendment to Services Agreement by and between the Registrant and NST Consulting, LLC, dated as of January 8, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.22		Third Amendment to Amended and Restated Sublease, by and between the Registrant and NST Consulting, LLC, dated as of February 8, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.23		Amendment to 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 June 15, 2016 (incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (File No. 333-212095), filed with the SEC on June 2, 2016).
10.24*		Fourth Amendment to Amended and Restated Sublease, by and between the Registrant and NST Consulting, LLC, dated as of October 24, 2016.
10.25*		Sixth Amendment to Services Agreement by and between the Registrant and NST Consulting, LLC, dated as of December 21, 2016.
10.26		Common Stock Sales Agreement, dated November 2, 2016, by and between the Registrant and Cowen and Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on November 2, 2016).
21.1		Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-212095), filed with the SEC on June 17, 2016).
23.1*		Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1*		Power of Attorney (contained on signature page hereto).

31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.

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32.1 *†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

*Filed herewith.

†This certification is being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

+Indicates management contract or compensatory plan.

#Confidential treatment has been granted with respect to portions of this exhibit (indicated by asterisks) and those portions have been separately filed with the SEC.

Item 16. Form 10-K Summary.

Not applicable.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACLARIS
THERAPEUTICS, INC.
By: /s/ Neal Walker
Neal Walker
President and Chief
Executive Officer

Date: March
15, 2017

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Neal Walker, Kamil Ali-Jackson and Frank Ruffo, jointly and severally, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place and stead, in any and all capacities, to sign this Annual Report on Form 10-K of Aclaris Therapeutics, Inc., and any or all amendments (including post-effective amendments) thereto, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that said attorneys-in-fact and agents, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Neal Walker Neal Walker	President, Chief Executive Officer and Director (Principal Executive Officer)	March 15, 2017
/s/ Frank Ruffo Frank Ruffo	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 15, 2017
/s/ Stephen A. Tullman	Chairman of the Board of Directors	

Stephen A. Tullman		March 15, 2017
/s/ Richard A. Bierly Richard A. Bierly	Director	March 15, 2017
/s/ Christopher Molineaux Christopher Molineaux	Director	March 15, 2017
/s/ Anand Mehra, M.D. Anand Mehra, M.D.	Director	March 15, 2017
/s/ William Humphries William Humphries	Director	March 15, 2017
/s/ Andrew Powell Andrew Powell	Director	March 15, 2017

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10.10+	

	Form of Stock Option Grant Notice and Stock Option Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.10 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
10.11+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement under 2015 Equity Incentive Plan (incorporated by reference to Exhibit 10.11 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
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10.20	#	Fourth Amendment to Services Agreement by and between the Registrant and NST Consulting, LLC, dated as of January 8, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.21	#	Fifth Amendment to Services Agreement by and between the Registrant and NST Consulting, LLC, dated as of January 8, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.22		Third Amendment to Amended and Restated Sublease, by and between the Registrant and NST Consulting, LLC, dated as of February 8, 2016 (incorporated by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
10.23		Amendment to 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 June 15, 2016 (incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (File No. 333-212095), filed with the SEC on June 2, 2016).
10.24*		Fourth Amendment to Amended and Restated Sublease, by and between the Registrant and NST Consulting, LLC, dated as of October 24, 2016.
10.25*		Sixth Amendment to Services Agreement by and between the Registrant and NST Consulting, LLC, dated as of December 21, 2016.
10.26		Common Stock Sales Agreement, dated November 2, 2016, by and between the Registrant and Cowen and Company, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on November 2, 2016).
21.1		Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-212095), filed with the SEC on June 17, 2016).
23.1*		Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1*		Power of Attorney (contained on signature page hereto).
31.1*		Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of

	2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32.1 *†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002.

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	XBRL Instance Document
101.INS*	
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

† This certification is being furnished solely to accompany this Annual Report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

+ Indicates management contract or compensatory plan.

Confidential treatment has been granted with respect to portions of this exhibit (indicated by asterisks) and those portions have been separately filed with the SEC.