Aclaris Therapeutics, Inc.
Form 10-K
March 18, 2019
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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, 2018 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

640 Lee Road, Suite 200

Wayne, PA 19087

(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 every Interactive Data File required to be submitted 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 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, a smaller reporting company or emerging growth company. See definitions of “large accelerated filer,” “accelerated filer”, “smaller reporting company” and “emerging growth company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer Accelerated filer Non-accelerated filer Smaller reporting company

Emerging growth company

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

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, 2018, 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 $528.2 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 15, 2019, 41,269,643 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 2019 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, or this Annual Report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, 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,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other 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 commercialize ESKATA and RHOFADE in the United States;
- our plans to develop and commercialize our drug candidates;
- the timing of our planned clinical trials of our drug candidates and the reporting of the results from these trials;
- the timing of the submission of our NDA for A-101 45% Topical Solution for the treatment of common warts;
- the timing of and our ability to obtain and maintain regulatory approvals for our drug candidates and products;
- the clinical utility of our drug candidates;
- our plans and expectations related to commercialization, marketing and manufacturing capabilities and strategy;
- our expectations about the willingness of patients to pay out of pocket for procedures using ESKATA for the treatment of raised SK;
- our expectations about the willingness of health care providers to use ESKATA for the treatment of raised SK and RHOFADE for the treatment of persistent facial erythema (redness) associated with rosacea;
- our expectations regarding coverage and reimbursement of our products and drug candidates, if approved;
- our plans to invest in a new research facility;
- the timing of our IND submissions for our immuno-inflammation drug candidates;
- our efforts to obtain five year NCE exclusivity from the FDA and a patent term extension from the USPTO for ESKATA;
- our intellectual property position;
- our plans to in-license or acquire additional drug candidates for other dermatological conditions to build a fully integrated biopharmaceutical company;
- our plans to pursue partnerships with third parties to commercialize our products outside of the United States;
- our expectations regarding competition;
- our expectations regarding our continued reliance on third parties;
- our expectations regarding the growth in the number of our employees and scope of operations;
- our expectations regarding our use of capital; 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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All brand names or trademarks appearing in this Annual Report, including ESKATA, ESKERIELE, RHOFADE, Physician's Wart Assessment and THWART, are the property of their respective owners. Unless the context requires otherwise, references in this report to "Aclaris," the "Company," "we," "us," and "our" refer to Aclaris Therapeutics, Inc. and i subsidiaries.

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PART I

Item 1. Business

Overview

We are a physician-led biopharmaceutical company focused on dermatological and immuno-inflammatory diseases. We have two commercial products and a diverse pipeline of drug candidates.

Our first commercial product, ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, is a proprietary formulation of high-concentration hydrogen peroxide topical solution which was approved by the U.S. Food and Drug Administration, or FDA, in December 2017 as an office-based prescription treatment for raised seborrheic keratosis, or SK, a common non-malignant skin tumor. We launched ESKATA in the United States in May 2018. We also submitted a Marketing Authorization Application, or MAA, for ESKATA in select countries in the European Union, Norway and Iceland in July 2017 using a decentralized procedure. In February 2019, we received approval from the Swedish Medical Products Agency to market ESKATA (hydrogen peroxide) cutaneous solution, 685 mg for the treatment in adults of SKs that are not pedunculated and have up to a maximum diameter of 15 millimeters each. We have also received approval to market ESKATA in the United Kingdom, Iceland and Belgium.

In November 2018, we acquired RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan Sales, LLC, or Allergan. RHOFADE was approved by the FDA in January 2017 for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults. Persistent facial redness is the most common sign of rosacea in most skin types.

We continue to develop our sales, marketing and product distribution capabilities for ESKATA and RHOFADE in order to support our commercialization efforts in the United States. We plan to continue to deploy sales representatives in approximately 50 territories in the United States which we believe will allow us to reach the health care providers in the United States with the highest potential for prescribing ESKATA and RHOFADE to their patients.

We are also developing another high-concentration formulation of hydrogen peroxide, A-101 45% Topical Solution, as a prescription treatment for common warts, also known as verruca vulgaris. On an annual basis, approximately 2.0 million people in the United States are diagnosed with common warts.

Additionally, in 2015, we in-licensed exclusive, worldwide rights from Rigel Pharmaceuticals, Inc., or Rigel, to certain inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions, including alopecia areata, or 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, or AT, and total hair loss on the scalp and body, known as alopecia universalis, or AU. We are also developing these JAK inhibitors for the treatment of vitiligo, androgenetic alopecia, or AGA, also known as male or female pattern baldness, and atopic dermatitis.

In 2016, in connection with the acquisition of Vixen Pharmaceuticals, Inc., or Vixen, 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 biopharmaceutical company.

In 2017, we acquired Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or Confluence. The acquisition of Confluence added small molecule drug discovery and preclinical development capabilities that allowed us to bring early-stage research and development activities in-house that we previously outsourced to third parties. We intend to leverage the proprietary KINect drug discovery platform to identify potential drug candidates that we may develop independently or with partners. We also acquired several preclinical drug candidates, including additional topical JAK inhibitors known as soft-JAK inhibitors, inhibitors of the MK-2 signaling pathway and inhibitors of interleukin-2-inducible T cell kinase, or ITK. Soft-JAK inhibitors may be topically applied and active in the skin, but will be rapidly metabolized and inactivated when they enter the bloodstream, which may result in significantly reduced systemic exposure. We also earn revenue from Confluence’s provision of contract research services to third parties.

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Our intellectual property portfolio contains issued patents directed to methods of use for high-concentration hydrogen peroxide compositions of at least 23% or more hydrogen peroxide, including ESKATA and A-101 45% Topical Solution, issued patents directed to methods of treating erythema associated with rosacea by administering oxymetazoline and pharmaceutical cream compositions of oxymetazoline, including RHOFADE and its approved use, and issued patents directed to our JAK inhibitor drug candidates, ATI-501 and ATI-502.

Our Drug Candidates

We have utilized our experience to establish a pipeline of drug candidates in dermatological and immuno-inflammatory diseases. Our pipeline of drug candidates is summarized in the table below:

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

We are 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, approximately 2.0 million people in the United States are diagnosed with common warts. As with SK lesions, cryosurgery is the most frequently used in-office treatment for common warts. Common warts can also be removed with slow-acting, over-the-counter products containing salicylic acid. We are not aware of any prescription drugs that have been approved by the FDA for the treatment of common warts.

We completed a Phase 2 clinical trial, WART-201, in August 2016 evaluating 40% and 45% concentrations of A-101 for the treatment of common warts, in which 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 subjects treated with the 45% concentration of A-101 compared to placebo. The PWA score is a four-point scale of the investigators assessment of the severity of a target wart at a particular time point.

In June 2017, we commenced two additional Phase 2 clinical trials, WART-202 and WART-203, of A-101 45% Topical Solution to assess the dose frequency in adult and pediatric subjects with common warts. Both trials evaluated the safety and efficacy of A-101 45% Topical Solution as compared to placebo, or vehicle. The two randomized, double-blind, vehicle-controlled trials were designed to understand the effects of dose frequency and to explore additional clinical endpoints that are now being further evaluated in our Phase 3 development program. We enrolled a total of 316 subjects at 34 investigational centers in the United States across both trials.

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The WART-202 trial evaluated 157 subjects who self-administered either A-101 45% Topical Solution or placebo once weekly through Day 56, for a total of 8 treatments. Each subject had between one and four warts at baseline. The trial achieved its primary endpoint, which was mean change from baseline in the PWA score of the target wart at Day 56 (one week after the last treatment). The mean reduction in PWA score at Day 56 on the target warts was 0.77 points in subjects who received A-101 45% Topical Solution, compared to a reduction of 0.23 points for the target warts that received placebo, a result that was also statistically significant ($p<0.001$).

The WART-203 trial evaluated 159 subjects who self-administered either A-101 45% Topical Solution or placebo twice weekly through Day 56, for a total of 16 treatments. Each subject had between one and six warts at baseline. The WART-203 trial achieved its primary endpoint, which was mean change from baseline in the PWA scale score at Day 56 (Visit 10 or one week after the last treatment). The mean reduction in PWA score at Day 56 on the target warts was 0.87 points in subjects who received A-101 45% Topical Solution, compared to a reduction of 0.17 points for the target warts that received placebo, a result that was statistically significant ($p<0.001$).

In March 2018, we reported final results, which included a 3-month drug-free follow-up phase, from the WART-203 clinical trial. In addition, in April 2018, we concluded the WART-202 clinical trial, in which we evaluated a different dosing regimen from the one used in the WART-203 clinical trial. In both of these clinical trials, subjects treated with A-101 45% Topical Solution achieved clinically and statistically significant outcomes for the primary and secondary endpoints of each of the trials. There were no treatment-related serious adverse events among subjects treated with A-101 45% Topical Solution.

Based on the results from these clinical trials, we held an end of Phase 2 meeting with the FDA. A twice-weekly dosing regimen is being evaluated in our two Phase 3 pivotal clinical trials, which we refer to as THWART-1 and THWART-2, of A-101 45% Topical Solution for the treatment of common warts, which we initiated in September 2018. We expect approximately 1,000 patients will be enrolled in these two trials by the end of March 2019. We expect to report data from both of these trials in the second half of 2019. In addition, in February 2019, we commenced an open-label safety extension trial investigating A-101 45% Topical Solution for the treatment of common warts. If the results of these three ongoing trials are positive, we expect to submit a New Drug Application, or NDA, to the FDA for A-101 45% Topical Solution for the treatment of common warts in the first half of 2020.

ATI-501 and ATI-502 for the Treatment of AA and Other Dermatological Indications

We are developing our JAK inhibitors, ATI-501 and ATI-502, which we in-licensed from Rigel, as potential treatments for AA and other dermatological indications. 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 AT, which is total scalp hair loss, and AU, which is total hair loss on the scalp and body. AA is estimated to affect up to 1.8% of people in the United States and 2.0% of people globally at some point during their lifetime, 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-501 as an oral treatment for AA. We submitted an investigational new drug application, or IND, to the FDA for ATI-501 for the treatment of AA in October 2016. Since the filing of the IND, we have conducted several Phase 1 clinical trials to evaluate the pharmacokinetic and pharmacodynamic, or PK/PD, properties of various formulations of ATI-501. Based on the results from these clinical trials, we selected an oral suspension and initiated a Phase 2 dose-response clinical trial of ATI-501 for the treatment of AA.

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We are developing ATI-502 as a topical treatment for AA, vitiligo, AGA and atopic dermatitis. We submitted an IND to the FDA for ATI-502 for the treatment of AA in July 2017. The following table summarizes the status of our ongoing Phase 2 clinical trials of ATI-501 and ATI-502, including their indications, trial objectives, number of subjects enrolled and expected timing for receipt of preliminary results:

Drug Candidate and Name of Trial	Indication	Objective	Subjects Enrolled	Preliminary Results Expected
ATI-501				
AUAT-201	AA	Dose-ranging	87	2H 2019
ATI-502				
AA-201	AA	Dose-ranging	129	2Q 2019
AA-202	AA	PK/PD	11	—(1)
AA-203	AA	Open-label study	80(2)	2021
AUATB-201	AA (Eyebrow)	Open-label study	12	—(3)
VITI-201	Vitiligo	Open-label study	34	2H 2019(4)
AGA-201	AGA	Open-label study	31	2Q 2019(5)
AD-201	Atopic Dermatitis	Open-label study	22	Mid-2019

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

(2)Approximate number of subjects per protocol.

(3)AUATB-201 interim data reported in December 2018.

(4)VITI-201 6-month interim data expected in the second quarter of 2019 and 12-month data expected in the second half of 2019.

(5)AGA-201 6-month data expected in the second quarter of 2019 and 12-month data expected in the second half of 2019.

JAK Inhibitors, ITK Inhibitors and MK-2 Inhibitors

In August 2017, we acquired Confluence. This acquisition added small molecule drug discovery and preclinical development capabilities that allowed us to bring early-stage research and development activities in-house that we

previously outsourced to third parties. We also acquired several preclinical drug candidates as part of the acquisition, including soft-JAK inhibitors, inhibitors of the MK-2 signaling pathway and ITK inhibitors. We expect to submit an IND to the FDA for ATI-450, an MK-2 inhibitor, for rheumatoid arthritis in mid-2019. If the IND is allowed by the FDA, we expect to initiate a Phase 1 and Phase 2 trial in the second half of 2019. We are considering developing ATI-450 for the treatment of rheumatoid arthritis, psoriasis, hidradenitis suppurativa, cryopyrin-associated periodic syndrome (CAPS), and pyoderma gangrenosum. We expect to submit an IND to the FDA for ATI-1777, a soft-JAK inhibitor, by the end of the first half of 2020. We are considering developing ATI-1777 for the treatment of several dermatological conditions, including atopic dermatitis, vitiligo and AA. We are considering developing our ITK inhibitors as a potential treatment for psoriasis, inflammatory dermatoses, and inflammatory bowel disease.

Our Commercial Products

ESKATA for the Treatment of Raised Seborrheic Keratosis

ESKATA is the first FDA-approved drug for the treatment of raised SKs. 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. 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 health care provider, 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.

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Our NDA for ESKATA for the treatment of raised SKs was approved by the FDA in December 2017. We launched ESKATA in the United States in May 2018. We submitted an MAA in select countries in the European Union, Norway and Iceland in July 2017 using a decentralized procedure. In February 2019, we received approval from the Swedish Medical Products Agency to market ESKATA (hydrogen peroxide) cutaneous solution, 685 mg for the treatment in adults of SKs that are not pedunculated and have up to a maximum diameter of 15 millimeters each. We have also received approval to market ESKATA in the United Kingdom, Iceland and Belgium. We are seeking a commercial partner or partners to market the medicine as an aesthetic skin treatment in various European countries with the brand name ESKATA in Finland, Iceland, Netherlands, Norway, Portugal, Spain, Sweden, Czech Republic and Belgium, and the brand name ESKERIELE in Austria, France, Germany, Ireland, Italy, and the United Kingdom.

In April 2018, we entered into an exclusive license agreement with Cipher Pharmaceuticals Inc., or Cipher, for the rights to obtain regulatory approval of and commercialize A-101 40% Topical Solution, which we market under the brand name ESKATA in the United States, in Canada for the treatment of SK, or the Cipher License Agreement. Under the Cipher License Agreement, Cipher is responsible for obtaining marketing approval in Canada for A-101 40% Topical Solution. Cipher submitted a New Drug Submission for A-101 40% Topical Solution for the treatment of raised SKs, which was accepted for review by Health Canada in December 2018. We will supply Cipher with finished product, and, if regulatory approval is obtained, Cipher will be responsible for distribution and commercialization of A-101 40% Topical Solution in Canada. Additionally, Cipher is responsible for all expenses related to regulatory and commercial activities for A-101 40% Topical Solution in Canada.

RHOFADE for the Treatment of Persistent Facial Erythema (Redness) Associated with Rosacea in Adults

In November 2018, we acquired from Allergan the worldwide rights to RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE. RHOFADE is indicated for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults. Rosacea is a chronic disease characterized by enduring facial redness and/or skin thickening. Other signs of rosacea include facial flushing, visible blood vessels (telangiectasia), blemishes resembling acne (papules and pustules), and eye irritation. Burning or stinging, swelling (edema), and dry appearance may accompany these signs. Persistent facial redness is the most common sign of rosacea in most skin types and, according to a survey of 1,289 patients with rosacea conducted by the National Rosacea Society, affects 71% of patients with rosacea.

RHOFADE was approved by the FDA in January 2017, and it became commercially available in the United States in May 2017.

Manufacturing and Supply

We do not have any manufacturing facilities. We rely on third parties for the manufacture of preclinical and clinical supplies for all of our drug candidates. We also rely on third parties for the commercial manufacture of ESKATA and RHOFADE.

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 ESKATA for the treatment of raised SKs and a number of other specified dermatological indications. The ten-year term commenced on the date of first commercial sale of ESKATA in the United States. We or PeroxyChem may terminate the supply agreement with prior written notice immediately for specified financial reasons, after a 10-business day and 60-day cure period for material monetary and material non-monetary breaches, respectively, and in the event of a force majeure event, 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.

We have entered into an exclusive commercial supply agreement with James Alexander Corporation, or James Alexander, for the manufacture of the finished dosage form of ESKATA. We must meet a minimum purchase requirement each year through 2022. In the event that we do not meet the minimum purchase requirements, James Alexander may, at its discretion, convert the agreement into a non-exclusive agreement. Additionally, during the term of the agreement, James Alexander will not manufacture any competitive product, as defined in the agreement. The term of the agreement with James Alexander is five years from the date of the first commercial sale of ESKATA in the United States and thereafter will be renewed automatically for one-year periods. Either party may terminate the agreement for any reason upon 180 days prior written notice. In addition, either party has the right to immediately terminate the supply agreement under certain circumstances, including (i) the other party files for bankruptcy, (ii) the other party materially breaches the

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supply agreement and such breach is not cured within a specified period and (iii) any required license, permit or certificate required of the other party to perform its obligations under the supply agreement is not approved or issued or is revoked by an applicable governmental regulatory authority.

We are also party to a manufacturing and supply agreement with a third party for the finished dosage form of RHOFADE.

Commercialization

We are commercializing ESKATA and RHOFADE ourselves in the United States, and intend to establish partnerships with third parties to commercialize them outside the United States in countries where we have received, or in the future may receive, approval. We are continuing to develop our sales, marketing and product distribution capabilities for ESKATA and RHOFADE in order to support our commercialization efforts in the United States. We plan to continue to deploy sales representatives in approximately 50 territories in the United States which we believe will allow us to reach the health care providers in the United States with the highest potential for prescribing ESKATA and RHOFADE to their patients. Our sales force is supported by sales and marketing management, internal sales and marketing, an advertising campaign, and commercial product distribution.

We sell ESKATA to one wholesaler, McKesson Specialty Care Distribution, or McKesson, which in turn resells ESKATA to health care providers. We have also entered into agreements with two group purchasing organizations, or GPOs, and may enter into additional agreements with other GPOs and corporate accounts that provide for administrative fees and discounted pricing in the form of volume-based rebates and chargebacks. We have no sales of ESKATA in countries outside of the United States. We have a no returns policy for ESKATA.

We believe dermatologists will be inclined to adopt ESKATA to treat their patients with SK lesions 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 ESKATA 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 began commercializing RHOFADE in the United States in December 2018. We currently rely on Allergan to distribute RHOFADE on our behalf pursuant to the terms of a transition services agreement while we develop our sales, marketing and distribution capabilities to support the commercialization of RHOFADE in the United States. We sell RHOFADE to wholesalers in the United States, which, in turn, distribute it to pharmacies that will ultimately fill patient prescriptions. We may also enter into arrangements with health care providers, pharmacy benefit managers, third-party payors, and GPOs which provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts, with respect to the purchase of RHOFADE. We have no sales of RHOFADE in countries outside of the United States.

It is estimated that 16.0 million people in the United States suffer from rosacea. Persistent facial redness is the most common sign of rosacea in most skin types. Although there are many branded and generic oral and topical medications prescribed to treat the papules and pustules of rosacea, they are not indicated for the treatment of persistent facial redness.

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

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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. Our products compete with, and any drug candidates that are approved and 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 ESKATA for the treatment of raised SKs, are likely to be its efficacy, safety, non-invasiveness, pain profile and ability to be administered by non-physician staff. With respect to ESKATA for the treatment of raised SKs, we are aware of the following companies that have treatments or 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; Epipharm, AG is developing a topical drug candidate targeting multiple skin conditions, including SK; and Pulse Biosciences, Inc. is developing a device 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 RHOFADE for the treatment of persistent facial erythema (redness) due to rosacea, we are aware of one other drug that is approved for this indication: MIRVASO (brimonidine) topical gel, 0.33%, which was approved by the FDA in 2013, and which is currently marketed by Galderma Laboratories, L.P.

With respect to A-101 45% Topical Solution for the treatment of common warts, we are aware of the following companies that have treatments or are developing treatments for common warts: Perrigo Company plc received a CE Mark approval for BL-5010, which it licenses from BioLineRx Ltd., as a novel over-the-counter treatment for the non-surgical removal of warts in the European Economic Area; and each of Nielsen BioSciences, Inc., Cutanea Lifesciences, Inc., Phio Pharmaceuticals Corp. and Verrica Pharmaceuticals Inc. is developing a drug candidate for the treatment of common warts. In addition, other drugs have been used off-label as treatments for common warts.

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

With respect to ATI-502 for the treatment of vitiligo, we are aware of one other company, Incyte Corporation, developing a topical JAK inhibitor for the treatment of vitiligo.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than ESKATA, RHOFADE or any other drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drug candidates 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

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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 products and 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 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 ESKATA and A-101 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 ESKATA and A-101 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 ESKATA and A-101 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 ESKATA and A-101 45% Topical Solution for the alleviation of acrochordons. The issued patents relating to the use of ESKATA and A-101 45% Topical Solution begin to expire in 2022, subject to any applicable patent term extension that may be available in a particular country.

We also own three issued U.S. patents and pending U.S., European and other foreign patent applications directed to various formulations comprising high-concentration hydrogen peroxide, including ESKATA and A-101 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. Our U.S. formulation, method of use and applicator patents expire in 2035 and any claims that issue from the pending formulation applications will expire in 2035, subject to any applicable patent term adjustment or extension that may be available in a particular country. In addition, we own a U.S. and PCT patent application directed to the use of high-concentration hydrogen peroxide, including ESKATA and A-101 45% Topical Solution, for the treatment of warts. We are in the process of filing national applications from this PCT patent application in Europe and other foreign countries. Any claims that issue from these applications will expire in 2037, subject to any applicable patent term adjustment or extension that may be available in a particular country.

With respect to our patent portfolio relating to RHOFADE, we exclusively license from Allergan a family of U.S. patents and pending applications, including three issued U.S. patents directed to methods of treating erythema associated with rosacea by administering alpha-1 adrenergic receptor agonists, including oxymetazoline, which cover

the approved use of RHOFADE, that expire between 2024 and 2028. We also own issued U.S. and European patents and pending U.S. and European applications, and other foreign country patents and applications directed to pharmaceutical cream compositions of oxymetazoline, including RHOFADE, that expire, or will expire, in 2031. We also own an issued U.S. patent and pending U.S. and European applications, and other foreign country applications directed to methods of treating facial erythema by topically administering once or twice daily 1% or 1.5% oxymetazoline hydrochloride, which cover the approved use of RHOFADE, that expire, or will expire, in 2035. We also own a family of patents in the United States, Europe and other foreign countries directed to methods of treating purpura by administering alpha-1 adrenergic receptor agonists, including oxymetazoline, which expire in 2028 and 2029 and a family of patents and applications in the United States, Europe and other foreign countries directed to methods of treating erythema associated with rosacea by administering oxymetazoline, which expire, or will expire, in 2032. We also exclusively sublicense from Allergan certain patents and applications in the United States and foreign countries owned by a third party for oxymetazoline for the treatment of rosacea or purpura by topical application, which expire in 2024.

With respect to ATI-501 and ATI-502, we exclusively license from Rigel multiple families of patents and applications relating to these compounds and the uses thereof in the field of dermatology. In particular, we exclusively license 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 license an issued U.S. patent and pending applications in the United States, Australia, Canada,

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the European Union and Japan with claims that cover the use of these compounds for the treatment of alopecia areata. The U.S. patent, and any claims that issue from these applications, expire, or 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-501 and ATI-502 that expire in 2023, subject to any applicable patent term extension that may be available in a particular country.

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 multiple U.S. patents with claims directed to the use of certain third-party JAK inhibitors 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., the European Union, 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 patent applications in the United States and other foreign countries directed to methods of inducing hair growth with JAK1, JAK2 or JAK3 inhibitors as well as 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 our inhibitors of the MK-2 signaling pathway, we own one U.S. patent and pending applications in the European Union and other foreign countries that cover ATI-450, our lead candidate. The U.S. patent expires in 2034 and any claims that issue from the pending applications expire in 2034, subject to any applicable patent term adjustment or extension that may be available in a particular country. We also own seven U.S. patents and pending foreign patent applications directed to other inhibitors of the MK-2 signaling pathway, which expire or will expire between 2031 and 2034, subject to any applicable patent term adjustment or extension that may be available in a particular country.

With respect to our soft-JAK inhibitors, we have filed two U.S. and PCT applications directed to various novel inhibitors of JAK1 and/or JAK3 and methods of using the same. Any claims that may issue would expire in 2038, subject to any applicable patent term adjustment or extension that may be available in a particular country.

With respect to our ITK inhibitors, we own multiple U.S. patents and pending applications in the United States and foreign countries directed to novel inhibitors of ITK and methods of using the same. The patents and pending applications, if issued, expire between 2035 and 2038, 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 products and 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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Acquisition and License Agreements

Assignment Agreement with the Estate of Mickey Miller and Finder's Services Agreement with KPT Consulting, LLC

In August 2012, we entered into an assignment agreement, or, as amended, the Assignment Agreement, with the Estate of Mickey Miller, or the Miller Estate, under which we acquired some of the intellectual property rights covering ESKATA 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 this agreement, we have the sole and exclusive right, but not the duty, to develop, obtain marketing approval for and commercialize ESKATA 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, in August 2012 we also entered into a separate finder's services agreement, or the 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 ESKATA 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 ESKATA in our Phase 3 clinical trial, a one-time milestone payment of $1.0 million in April 2017 upon the achievement of a specified regulatory milestone, and a one-time milestone payment of $1.5 million in May 2018 upon the achievement of a specified commercial milestone. Under the terms of the Finder's Services Agreement, we are obligated to make an additional milestone payment of $3.0 million upon the achievement of a specified commercial milestone. Under each of the Assignment Agreement and the Finder's Services Agreement, we are also obligated to pay royalties on sales of ESKATA or related products, at low single-digit percentages of net sales, subject to reduction in specified circumstances. 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-501 and ATI-502, or the Rigel License Agreement. Under this agreement, we intend to develop these JAK inhibitors for the treatment of AA and other dermatological conditions. We are required to use commercially reasonable efforts to develop and commercialize at least one product. We paid Rigel an upfront nonrefundable 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 Rigel License 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 Rigel License 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 Rigel License 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 Rigel License 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.

In March 2016, we entered into a stock purchase agreement, or the Vixen Agreement, with Vixen and JAK1, LLC, JAK2, LLC and JAK3, LLC, or together, the Selling Stockholders, and Shareholder Representative Services LLC, 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 our wholly-owned subsidiary. 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 through March 2022, with such amounts being creditable against specified future payments that may be paid under the Vixen Agreement.

Under the Vixen 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.

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.

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 as amended, the Columbia License Agreement. Pursuant to the Columbia License Agreement, we have 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. Our 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 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.

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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.

Agreement and Plan of Merger with Confluence

In August 2017, we entered into an Agreement and Plan of Merger, or the Confluence Agreement, with Confluence, Aclaris Life Sciences, Inc., our wholly-owned subsidiary, or Merger Sub, and Fortis Advisors LLC, as representative of the equity holders of Confluence. Pursuant to the terms of the Confluence Agreement, the Merger Sub merged with and into Confluence, with Confluence surviving as our wholly-owned subsidiary, resulting in our acquisition of 100% of the outstanding shares of Confluence. We paid $10.3 million in cash and issued 349,527 shares of our common stock with a fair value of $9.7 million to the Confluence equity holders.

In November 2018, we achieved a development milestone specified in the Confluence Agreement. The milestone payment to the former Confluence equity holders was comprised of $2.5 million in cash and 253,208 shares of our common stock with a fair value of $2.2 million. We also agreed to pay the former Confluence equity holders aggregate additional contingent consideration of up to $75.0 million, based upon the achievement of certain regulatory and commercial milestones set forth in the Confluence Agreement. In addition, we have agreed to pay the former Confluence equity holders specified future royalty payments calculated as a 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. In addition, if we sell, license or transfer any of the intellectual property acquired from Confluence to a third party, we will be obligated to pay the former Confluence equity holders a portion of any incremental consideration (in excess of the development and milestone payments described above) that we receive from such sale, license or transfer in specified circumstances.

Asset Purchase Agreement with Allergan

In November 2018, we closed the acquisition of the worldwide rights to RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan, pursuant to the terms of the Asset Purchase Agreement dated as of October 15, 2018, or as amended, the Asset Purchase Agreement.

At the closing of the acquisition, we paid total cash consideration of approximately $66.1 million, consisting of approximately $59.6 million paid to Allergan and $6.5 million placed in escrow. We have also agreed to pay Allergan a one-time payment of $5.0 million upon the achievement of a specified development milestone related to the potential development of an additional dermatology product. In addition, we have agreed to pay Allergan specified

royalty payments, ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to a particular product, such as RHOFADE, have expired or, if later, November 30, 2028. In addition, we have agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Members of our management team, including Neal Walker, Frank Ruffo, Christopher Powala and Stuart Shanler, as well as Stephen Tullman, the chairman of our board of directors, are former stockholders of Vicept Therapeutics, Inc., and Dr. Shanler is also a current member of Aspect Pharmaceuticals, LLC. In their capacities as current or former holders of equity interests in these entities, these individuals may be entitled to receive a portion of the potential future payments payable by us.

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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 ones we are commercializing and developing. A drug candidate 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. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations require the expenditure of substantial time and resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, approval process or after approval may subject an applicant and/or sponsor to a variety of administrative or judicial sanctions, including refusal by regulatory authorities to approve applications, withdrawal of an approval, imposition of a clinical hold, import/export delays, issuance of warning letters and untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, restitution, disgorgement of profits, or civil or criminal investigations and penalties brought by FDA and the Department of Justice or other governmental entities.

United States Government Regulation

NDA Approval Processes

In the United States, the FDA regulates drug and medical device products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and its implementing regulations. A-101 45% Topical Solution is comprised of both a drug component (the hydrogen peroxide solution) and a pen-type applicator. 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 A-101 45% Topical Solution for the treatment of common warts, but this could change during the course of the FDA's review of the 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, and 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

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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 GCP 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 IRB at each institution participating in the clinical trial must review and approve the protocol before the clinical trial commences at that institution and must also approve the information regarding the trial and the consent form that must be provided to each research subject or the subject's legal representative, monitor the study until completed and otherwise comply with IRB regulations.

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

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

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

Clinical trials are inherently uncertain, and Phase 1, Phase 2 and Phase 3 testing may not be successfully completed. The FDA or the sponsor may suspend a clinical trial at any time for a variety of reasons, including a finding that the

research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB can suspend or terminate approval of a clinical trial at its institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In some cases, clinical trials are overseen by an independent group of qualified experts organized by the trial sponsor, which is called the clinical monitoring board or data safety monitoring board. This group provides authorization for whether or not a trial may move forward at designated check points. These decisions are based on the limited access to data from the ongoing trial.

During the development of a new drug, sponsors are given opportunities to meet with the FDA at certain points. These points may be prior to the submission of an IND, at the end-of-Phase 2 and before 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.

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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.

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

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

Failure to comply with the applicable U.S. 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. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. 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. If market exclusivity is granted for an NCE, during the exclusivity period, the FDA may not accept for review or approve 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 prohibits the FDA from approving an ANDA, or a 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Clinical investigation exclusivity 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 for the same drug. 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, or 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 European Union. 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 EEA 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 EEA's regulatory authorities to be a new chemical entity, and products may not qualify for data exclusivity.

Other Health Care Laws

Health care providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of ESKATA, RHOFADE and any other drug candidates for which we obtain marketing approval. Our arrangements with third-party payors, health care professionals and customers may expose us to broadly applicable fraud and abuse and other health care 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.

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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 health care 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 health care 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 health care 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, or 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 activities relating to the sale and marketing of our products 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 for each separate false claim, the potential for exclusion from participation in federal health care programs, and, although the federal civil False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes. For example, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created federal criminal statutes that prohibit among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program, including private third-party payors, knowingly and willfully embezzling or stealing from a health care benefit program, willfully obstructing a criminal investigation of a health care 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 health care benefits, items or services. Like the Anti-Kickback Statute, the Affordable Care Act amended the intent standard for the health care 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.

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.

In addition, legislation imposing marketing restrictions and transparency requirements on pharmaceutical manufacturers has been enacted at the state and federal levels. For example, the Affordable Care Act imposed, among other things, 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

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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 for "knowing failures." Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices, require registration of certain employees engaged in marketing activities in the location, and/or require the tracking and reporting of gifts, compensation and other remuneration to physicians.

Because we are commercializing and intend to commercialize products that are reimbursed under a federal health care program and other governmental health care programs, we intend to continue 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 significant 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 health care 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 health care 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 HIPAA 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 attorneys’ fees and costs associated with pursuing federal civil actions. In addition, certain state laws govern the privacy and security of health information in certain circumstances, some of which are more stringent than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties.

Health Care Reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain health care 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 health care industry. The Affordable Care Act was designed to expand coverage for the uninsured and at the same time containing overall health care 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 70% 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 health care services.

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Since its enactment there have been judicial and Congressional challenges to, as well efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January 22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, the Centers for Medicare & Medicaid Services, or CMS, published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump Administration and CMS, has stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, President Obama 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, including the BBA, will stay in effect through 2027, 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. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. At the federal level, the Trump Administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or

in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump Administration released a “Blueprint”, or plan, to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal health care programs, incentivize manufacturers to lower the list price of their products, and reduce the out-of-pocket costs of drug products paid by consumers. The Department of Health and Human Services, or HHS, has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the

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purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump Administration have both stated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level, legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

The Affordable Care Act, as well as other federal and state health care 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 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

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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.

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 for the first permitted commercial marketing of a drug product. 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.

Coverage and Reimbursement

We do not expect third-party payors to cover and reimburse health care providers who use ESKATA on patients for the treatment of raised SKs. Third-party 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, ESKATA may 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 ESKATA. Accordingly, the commercial success of ESKATA depends on the extent to which patients are willing to pay out of pocket for the in-office procedure using our product. By contrast, in the case of RHOFADE, we believe our success will depend on continued coverage and adequate reimbursement, and in the case of A-101 45% Topical Solution for the treatment of

common warts or our other drug candidates, if approved, on obtaining and maintaining coverage and adequate reimbursement, for a prescription treatment or in the absence of coverage and adequate reimbursement, on the extent to which patients will be willing to pay out of pocket for our prescription drug products.

Third-party payors determine which prescription drug products they will cover and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including: the third-party payor's determination that a product is safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals or current clinical practice guidelines; and whether there are competitive products, either branded or generic, and the pricing of those products. Many private third-party payors, such as managed care plans, manage access to drug products' coverage partly to control costs for their plans, and may use drug formularies and medical policies to limit their exposure. Obtaining and maintaining favorable reimbursement can be a time-consuming and expensive process, and we may not be able to negotiate or continue to negotiate reimbursement or pricing terms for our products with third-party payors at levels that are profitable to us, or at all.

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. Accordingly, these updates could impact the demand for RHOFADE or A-101 45% Topical Solution for the treatment of common warts or our other drug candidates, if approved. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of

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operations could be adversely affected by the Affordable Care Act and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential partners could receive for any of our products and could adversely affect our profitability.

Foreign governments also have their own health care 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 our products under any foreign reimbursement system. In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take up to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of our product to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Employees

As of December 31, 2018, we had 169 full-time and part-time employees. All of our employees are located in the United States. None of our employees are represented by a labor union or covered by a collective bargaining agreement. We consider our relationship with our employees to be good.

Corporate Information

We were incorporated under the laws of the State of Delaware in July 2012. Our principal executive offices are located at 640 Lee Road, Suite 200, Wayne, PA 19087. 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 Exchange Act 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.

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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 Business, 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 have a limited operating history. Since inception, we have incurred significant net losses. We incurred net losses of $132.7 million and $68.5 million for the years ended December 31, 2018 and 2017, respectively. As of December 31, 2018, we had an accumulated deficit of $292.2 million. We have financed our operations since inception primarily 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 currently have two products, ESKATA and RHOFADE, that generate revenue from product sales.

We have devoted substantially all of our financial resources and efforts to the development of our drug candidates, including preclinical studies and clinical trials, and beginning in 2017, to the commercialization of our products. Our net losses may fluctuate significantly from quarter to quarter and year to year. We expect to continue to incur significant expenses and operating losses over the next several years as we:

- continue to commercialize ESKATA and RHOFADE in the United States;
- continue our ongoing clinical trials evaluating A-101 45% Topical Solution for the treatment of common warts and pursue marketing approvals for A-101 45% Topical Solution and for any other drug candidates that successfully complete clinical trials;
- initiate and continue clinical trials of our other drug candidates, including ATI-501 for the treatment of AA and ATI-502 for the treatment of AA, vitiligo, AGA and atopic dermatitis;
- continue to develop our preclinical drug candidates, including ATI-450, an MK-2 inhibitor, ATI-1777, a soft-JAK inhibitor, and our ITK inhibitors;
- seek to discover and develop additional drug candidates;
- continue to develop a commercialization infrastructure and scale up external manufacturing and distribution capabilities to commercialize our products and 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 commercialization efforts; and
- incur additional legal, accounting, investor relations and other administrative expenses in operating as a public company.

To become and remain profitable, we must succeed in commercializing our products and 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 products and drug candidates for which we have obtained and may obtain marketing approval, as well as discovering and developing additional drug candidates. We are only in the early 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.

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For ESKATA, RHOFADE and for any drug candidates for which we are successful in obtaining marketing approval, our revenue is and will continue to 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, if any, and whether we own the commercial rights for that territory. If the number of our addressable patients is not as significant as we estimate, the indication approved by regulatory authorities is narrower than we expect, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not generate significant revenue from sales of such drug products, even if approved.

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

Even if we achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis. Our failure to become and remain profitable would depress the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, obtain 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 continue to commercialize ESKATA and RHOFADE and conduct clinical trials of and seek marketing approval for our drug candidates. In addition, ESKATA and RHOFADE, and our drug candidates, if approved, may not achieve commercial success. In addition, if we obtain marketing approval for A-101 45% Topical Solution for the treatment of common warts or any other drug candidates that we develop, we expect to incur additional 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 our continuing operations as a public company.

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As of December 31, 2018, we had cash, cash equivalents and marketable securities of $168.0 million. We believe that our existing cash, cash equivalents and marketable securities 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 products or drug candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the extent to which we in-license or acquire additional drug candidates and technologies;
- the number and development requirements of the drug candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting pre-clinical and clinical trials for our drug candidates;
- the cost of commercializing ESKATA and RHOFADE and 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 received from commercial sales of ESKATA and RHOFADE and any of our drug candidates for which we receive marketing approval;
- the progress of obtaining marketing approval for ESKATA in select countries in the European Union and Norway;
- our ability to establish collaborations to commercialize ESKATA and RHOFADE outside the United States;
- 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; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future products or drug candidates, if any, as a result of licenses to, or partnership or collaborations with, third parties.

We expect that we will require additional capital to complete the clinical trials for and potentially commercialize A-101 45% Topical Solution for the treatment of common warts, to complete the clinical development of ATI-501 and ATI-502, to develop our preclinical compounds, to support our discovery efforts, and to pursue in-licenses or acquisitions of other drug candidates. We also expect to incur significant expenses related to the commercialization of ESKATA and RHOFADE, including product manufacturing, sales, marketing, advertising and distribution costs. In addition, in 2019 we plan to invest in a new research facility for our drug discovery operations. 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.

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

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

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, some of which may be beyond our control. We cannot assure you that we will maintain a level of

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

Because our long-term indebtedness bears interest at rates that fluctuate with changes in certain prevailing short-term interest rates, we are vulnerable to interest rate increases.

Our long-term indebtedness bears interest at a fluctuating interest rate based on the London interbank offered rate for deposits of U.S. dollars (LIBOR). LIBOR tends to fluctuate based on general interest rates, rates set by the Federal Reserve and other central banks, the supply of and demand for credit in the London interbank market and general economic conditions. On July 27, 2017, the Financial Conduct Authority (the authority that regulates LIBOR) announced that it intends to stop compelling banks to submit rates for the calculation of LIBOR after 2021. It is unclear whether new methods of calculating LIBOR will be established such that it continues to exist after 2021. The U.S. Federal Reserve, in conjunction with the Alternative Reference Rates Committee, is considering replacing U.S. dollar LIBOR with a newly created index, calculated with a broad set of short-term repurchase agreements backed by treasury securities. It is not possible to predict the effect of these changes, other reforms or the establishment of alternative reference rates in the United States or elsewhere. To the extent these interest rates increase, our interest expense will increase, in which event we may have difficulties making interest payments and funding our other fixed costs, and our available cash flow for general corporate requirements may be adversely affected.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies, products or drug candidates.

Until such time, if ever, as we can generate substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and collaboration agreements. To the extent that we raise additional capital through the sale of equity securities 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, products 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 or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development or future commercialization efforts or grant rights to third parties to develop and market technologies, products or drug candidates that we would otherwise prefer to develop and market ourselves.

We have a limited operating history and a limited 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 ESKATA for the treatment of raised SKs, including undertaking preclinical studies and conducting clinical trials, and acquiring new drug candidates and related intellectual property. We launched ESKATA in the United States in May 2018 and acquired RHOFADE in November 2018. We have had limited time to demonstrate our ability to successfully 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 of these products. 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

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a longer history of commercializing drugs. We may also encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Our estimates of variable consideration related to revenue recognition from product sales are difficult to estimate, and if our estimates differ significantly from actual product sales, we will be required to record an adjustment in a subsequent period.

Our estimates of variable consideration related to revenue recognition from product sales are difficult to estimate as they are based on multiple assumptions which may prove to be incorrect. For example, we pay certain third-party payors rebates with respect to the utilization of RHOFADE which are based on contractual percentages applied to the amount of RHOFADE prescribed to patients who are covered by the plan or the organization with which the third-party payor contracts. We have a savings card program to provide assistance to eligible patients with out-of-pocket costs for the patient's usage of RHOFADE. Reductions to product sales for the savings card program are estimated based on actual and expected program utilization. We recognize revenue from product sales at the point the customer obtains control, which generally occurs upon delivery, and also include estimates of variable consideration in the same period revenue is recognized. Components of variable consideration include trade discounts and allowances, product returns, government rebates, discounts and rebates, other incentives such as patient co-pay assistance, and other fee for service amounts. Our estimates of variable consideration are based on assumptions relating to, among other things, the mix of patients who purchase RHOFADE who are fully insured, underinsured and uninsured and the utilization of our savings card program, rebates, discounts and other pricing concessions and fees. If our estimates of variable consideration differ significantly from actual product sales, we will be required to record an adjustment in a subsequent period to reported product sales and earnings.

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 or commercialization of our drug candidates could be delayed.

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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 have invested significant efforts and financial resources in the development of our drug candidates and the identification of potential drug candidates. Our ability to generate substantial revenue from our drug candidates will depend heavily on the successful development, marketing approval and eventual commercialization of these drug candidates. The success of any drug candidates that we develop, including A-101 45% Topical Solution, ATI-501 and ATI-502, 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;
- receipt of timely approvals from applicable regulatory authorities;
- commercial launch of our drug candidates, if approved;
- acceptance of our drug candidates, if approved, by patients, the medical community and third-party payors, and willingness of patients to pay out of pocket for our drug candidates when third-party payor coverage and reimbursement is limited or unavailable;
- our success in educating physicians and patients about the benefits, administration and use of our drug candidates, if approved;
    - the prevalence and severity of adverse events experienced with our drug candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative treatments for the proposed indications of our drug candidates;
- 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 any 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 our drug candidates currently in development 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 regulatory approval 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 for use in the target indication. Clinical testing is expensive, difficult to design and implement, can take many years to complete and is inherently uncertain as to outcome.

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A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, and interim results of a clinical trial do not necessarily predict final results. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their drug candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

We 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.

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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.

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 subjects 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 subjects. Subject 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 subject enrollment taking longer than anticipated or subject 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 subjects 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

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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.

Additionally, if we or others identify undesirable side effects caused by our 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 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 biopharmaceutical 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.

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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 45% Topical Solution for the treatment of common warts, ATI-501 and ATI-502 for the treatment of AA and ATI-450 for the treatment of rheumatoid arthritis. As a result, we may forego or delay pursuit of opportunities with other drug candidates or for other indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial drugs or profitable market opportunities. Our spending on current and future development programs and drug candidates for specific indications may not yield any commercially viable drugs. If we do not accurately evaluate the commercial potential or target market for a particular drug candidate, we may relinquish valuable rights to that drug candidate through collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such drug candidate.

Risks Related to the Commercialization of ESKATA, RHOFADE and Our Drug Candidates

ESKATA, RHOFADE and any of our drug candidates that receive marketing approval 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.

ESKATA, RHOFADE and any of our drug candidates that receive marketing approval, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If ESKATA, RHOFADE and 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 ESKATA, RHOFADE and, if approved, any drug candidate, 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 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 ESKATA for the treatment of raised SKs;
- the availability of third-party payor 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.

We have a savings card program for RHOFADE to provide assistance to eligible patients with out-of-pocket costs for the patient's usage of RHOFADE. Changes to or elimination of the savings card program could adversely affect the frequency with which health care providers prescribe RHOFADE, the availability of RHOFADE at pharmacies and the demand for and use of RHOFADE by patients.

If we are unable to establish effective sales, marketing and distribution capabilities for ESKATA and RHOFADE, or a drug candidate that may receive marketing approval, we may not be successful in commercializing ESKATA or RHOFADE or those drug candidates if and when they are approved.

To achieve commercial success for ESKATA and RHOFADE and any drug candidate for which we may obtain marketing approval, we will need to build a focused sales and marketing infrastructure to market or co-promote ESKATA and RHOFADE and, if approved, some of our drug candidates in the United States. We have begun this process and have hired a sales force for ESKATA and RHOFADE, but 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

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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 health care providers or persuade adequate numbers of health care providers to prescribe our products;
- 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 effective 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 effective sales, marketing and distribution capabilities, either on our own or in collaboration with third parties, we will not be successful in commercializing our products or drug candidates.

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

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

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

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

With respect to A-101 45% Topical Solution for the treatment of common warts, we are aware of one company that received a CE Mark approval for an over-the-counter treatment for the non-surgical removal of warts, and 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.

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

With respect to ATI-502 for the treatment of vitiligo, we are aware of one other company developing a topical JAK inhibitor for the treatment of vitiligo.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than ESKATA, RHOFADE 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.

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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 ESKATA for the treatment of raised SKs and, accordingly, our success will be dependent upon the willingness of patients to pay out of pocket for ESKATA.

We do not expect third-party payors to cover and reimburse providers who use ESKATA on patients for the treatment of raised SKs. Third-party 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, ESKATA 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 ESKATA. Accordingly, the commercial success of ESKATA depends on the extent to which patients will be willing to pay out of pocket for the in-office procedure.

The success of RHOFADE and A-101 45% Topical Solution for the treatment of common warts or our other drug candidates, if approved, will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these products.

In the case of RHOFADE, we believe our success will depend on continued coverage and adequate reimbursement, and in the case of A-101 45% Topical Solution for the treatment of common warts or our other drug candidates, if approved, on obtaining and maintaining coverage and adequate reimbursement, for a prescription treatment or in the absence of coverage and adequate reimbursement, on the extent to which patients will be willing to pay out of pocket for our prescription drug products.

Third-party payors determine which prescription drug products they will cover and establish reimbursement levels. Reimbursement by a third-party payor may depend upon a number of factors, including: the third-party payor’s determination that a product is safe, effective, and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals or current clinical practice guidelines; and whether there are competitive products, either branded or generic, and the pricing of those products. Many private third-party payors, such as managed care plans, manage access to drug products’ coverage partly to control costs for their plans,

and may use drug formularies and medical policies to limit their exposure. Obtaining and maintaining favorable reimbursement can be a time-consuming and expensive process, and we may not be able to negotiate or continue to negotiate reimbursement or pricing terms for our products with third-party payors at levels that are profitable to us, or at all.

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. Accordingly, these updates could impact the demand for RHOFADE or A-101 45% Topical Solution for the treatment of common warts or our other drug candidates, if approved. Our products may not be considered cost effective, and government and third-party private health insurance coverage and reimbursement may not be available to patients or sufficient to allow us to sell our products on a competitive and profitable basis. Our results of operations could be adversely affected by the Affordable Care Act and by other health care reforms that may be enacted or adopted in the future. In addition, increasing emphasis on managed care in the United States will continue to put pressure on the pricing of pharmaceutical products. Cost control initiatives could decrease the price that we or any potential partners could receive for any of our products and could adversely affect our profitability. We cannot predict how pending and future health care legislation will impact our business, and any changes in coverage and reimbursement that further restricts coverage of our products or drug candidates could harm our business.

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Foreign governments also have their own health care 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 our products under any foreign reimbursement system. In some foreign countries, including major markets in the European Union and Japan, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take up to 12 months or longer after the receipt of regulatory marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a pharmacoeconomic study that compares the cost-effectiveness of our product to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our products is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any of our products or drug candidates 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 an even greater risk relating to the commercialization of ESKATA and RHOFADE. 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, product liability claims may result in:

- decreased demand for our products or any drug candidates 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;
- product recall or withdrawal from the market or labeling, marketing or promotional restrictions; and
- the inability to commercialize our products or any drug candidates that we may develop.

We currently hold $10 million in product liability insurance coverage in the aggregate, with a per incident limit of $10 million, which may not be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may need to increase our insurance coverage and 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.

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 engage CROs to conduct clinical trials of our drug candidates. 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.

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

We contract with third parties for the manufacture of commercial quantities of ESKATA and RHOFADE and for the supply of our drug candidates for preclinical and clinical testing. This reliance on third parties increases the risk that we will not have sufficient quantities of ESKATA, RHOFADE or 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. We currently rely, and expect to continue to rely, on third parties for the manufacture of commercial quantities of ESKATA and RHOFADE and supply of our drug candidates for preclinical and clinical testing. 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 ESKATA for the treatment of raised SKs, a manufacturing and supply agreement with a third party for the finished dosage form of RHOFADE, and an exclusive commercial supply agreement with James Alexander for the manufacture of the finished dosage form of ESKATA. This reliance on third parties increases the risk that we will not have sufficient quantities of our products or 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.

The facilities used by our contract manufacturers to manufacture our products and 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 for our products or drug candidates in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to commercialize our products and to develop, obtain regulatory approval for or market, if approved, our drug candidates.

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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 our third party suppliers for the active pharmaceutical ingredients in ESKATA and RHOFADE;
- the possible increase in costs by our manufacturers for the finished dosage forms of ESKATA and RHOFADE; 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 products, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our products.

Our products and drug candidates that we may develop may compete with other products and drug candidates 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 ESKATA or RHOFADE.

If our current contract manufacturers cannot perform as agreed, we may be required to replace such manufacturers. We may incur added costs and delays in identifying and qualifying any such replacement.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. Our current and anticipated future dependence upon others for the manufacture of our products and drug candidates may adversely affect our future profit margins and our ability to commercialize any drug candidates 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.

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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 products or 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 products or drug candidates, which may cause collaborators to cease to devote resources to the commercialization of our drug candidates, if approved;
- 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 drug candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of drug candidates, might lead to additional responsibilities for us with respect to drug candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable drug candidates.

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

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

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

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

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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.

Our sublease could terminate if the master lease is terminated for any reason, thus terminating our rights to our corporate headquarters.

We sublease space for our corporate headquarters. While the term of the sublease extends until October 2023, if for any reason the master lease is terminated or expires prior to October 2023, our sublease will also automatically terminate. In such an event, we would need to obtain a new direct lease with the master landlord or negotiate and enter into a new lease for office space at a different location, which we may not be able to do on commercially reasonable terms, if at all.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our products or 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, products 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 products and drug candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our products and drug candidates.

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

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

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

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commercialize our technology or drugs and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications that we own, or license is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future drug candidates.

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

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

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

Competitors may infringe our issued patents or other intellectual property. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents or that our patents are invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement or insufficient written description. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution. Third parties may also raise similar claims before the USPTO, in post-grant proceedings such as ex parte reexaminations, inter partes review, or post-grant review, or oppositions or similar administrative proceedings outside the United States, in parallel with litigation or, even outside the context of litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the

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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 products and drug candidates. Such a loss of patent protection would harm our business.

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

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

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

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

With respect to ATI-501 and ATI-502, if we do not elect to exercise our first right to do so, Rigel may enforce the licensed patents relating to ATI-501 and ATI-502 against any infringing third party in the field of dermatology. In addition, Rigel has the first right, but not the obligation, to enforce the licensed patents relating to ATI-501 and ATI-502 against any infringing party outside of the field of dermatology. With respect to the licensed patents from Columbia University, Columbia University has the first right to initiate, control and defend any proceedings related to the validity, enforceability or infringement of the licensed 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.

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

We exclusively license from Allergan a family of U.S. patents and applications relating to methods of treating erythema associated with rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which expire between January 2024 and May 2028. This patent family covers the approved use of RHOFADE. This patent family is also subject to an exclusive license granted by Allergan to a third party, which places obligations and limitations

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on our ability to prosecute, maintain and enforce such patents solely as they relate to an alpha adrenoreceptor agonist that is not oxymetazoline.

If we breach our license agreement with Rigel, it could compromise our development and commercialization efforts for our JAK inhibitors ATI-501 and ATI-502.

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-501 and ATI-502 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 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.

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-501 or ATI-502.

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

Filing, prosecuting and defending patents on our products and drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. For example, the use of ESKATA for the treatment of raised SKs is currently covered by patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. The use of A-101 45% Topical Solution for the treatment of warts is currently covered by issued patents in the United States, Australia, India and New Zealand, but not in the European Union or other countries. A U.S. patent is issued, and patent applications are pending in the United States, the European Union and other foreign countries directed to high-concentration hydrogen peroxide formulations, including ESKATA and A-101 45% Topical Solution and methods of use. With respect to RHOFADE, the family of patents and applications relating to methods of treating erythema associated with rosacea by topically administering oxymetazoline or other alpha-1 adrenoreceptor agonists, which expire between January 2024 and May 2028, is not filed outside of the United States. Accordingly, the patent protection for RHOFADE outside of the United States is based upon a family of patents and applications in the United States, the European Union and other major foreign markets that cover certain cream formulations of oxymetazoline, including RHOFADE, which expires in December 2031 and a family of patents and applications in the United States, the European Union and other major foreign markets relating to methods of treating facial erythema associated with rosacea by topically administering once or twice daily 1% or 1.5% oxymetazoline, which expires in June 2035. The approved use of RHOFADE

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may also be covered by certain patents and applications in the United States, the European Union and other major foreign markets that expire in May 2024, which we exclusively sublicense from Allergan.

Our JAK inhibitors, ATI-501 and ATI-502, are currently covered in patents and applications in the United States, the European Union, and other major foreign markets. Additionally, U.S. and Japanese patents have issued in the patent portfolio licensed from Columbia University, which are directed to the use of certain third party JAK inhibitors for the treatment of hair loss disorders and applications are pending in the United States, the European Union, Japan and South Korea. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our invention in such countries. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and may export otherwise infringing products to territories where we have patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with our products and 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 products and drug candidates. For example, we exclusively license patents from Allergan related to the use of alpha-1 adrenergic agonists for the treatment of erythema related to rosacea, which cover the approved use of RHOFDADE, and we exclusively license intellectual property from Rigel in the field of dermatology related to our JAK inhibitors, ATI-501 and ATI-502. 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 products and 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 in order to develop, use, manufacture, sell and commercialize ATI-501 and ATI-502 in the field of dermatology. Rigel has retained the rights under such intellectual property to develop, use, manufacture, sell and commercialize ATI-501 and ATI-502 outside of the field of dermatology. If Rigel 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 drug candidates, if approved. Rigel also retained the intellectual property rights to develop, use, manufacture, sell and commercialize other structurally similar JAK inhibitors. If Rigel commercializes a structurally similar JAK inhibitor, such a product could directly compete with our drug candidates, if approved.

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

If we are found to infringe a third party's intellectual property rights, we could be required to obtain a license from such third party to continue developing and marketing our drugs and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the infringing technology or drug. In addition, we could be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could hinder current commercialization efforts of our products or prevent us from commercializing our drug candidates, if approved, 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 licensors' employees were previously employed at other biotechnology or pharmaceutical companies. Although we and our licensors 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.

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

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

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

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

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

If a third party files an ANDA or 505(b)(2) application for a generic of ESKATA or RHOFADE, and relies in whole or in part on studies conducted by or for us, the third party will be required to certify to the FDA that either: (1) there is no patent information listed in the FDA's Orange Book with respect to our NDA for the applicable approved drug; (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, or that such patents are invalid, is called a paragraph IV certification. If the third party submits a paragraph IV certification to the FDA, a notice of the paragraph IV certification must also be sent to us once the third party's ANDA is accepted for filing by the FDA. We may then initiate a lawsuit to defend the patents identified in the notice. The filing of a patent infringement lawsuit within 45 days of receipt of the notice automatically prevents the FDA from approving the third party's ANDA until the earliest of 30 months or the date on which the patent expires, the lawsuit is settled, or the court reaches a decision in the infringement lawsuit in favor of the third party. If we do not file a patent infringement lawsuit within the required 45-day period, the third party's ANDA will not be subject to the 30-month stay of FDA approval. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be very expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with ESKATA or RHOFADE. We are aware that a third party generic pharmaceutical company completed a Phase 3 clinical trial in March 2018 evaluating the reduction in erythema in adults with moderate to severe facial erythema associated with rosacea with a 1% oxymetazoline topical cream in comparison to an oxymetazoline reference listed drug. Such a clinical trial could serve as the basis for filing an ANDA or 505(b)(2)

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application for a generic of RHOFADE that relies in whole or in part on studies conducted by Allergan, triggering the potential for a paragraph IV certification and subsequent patent infringement lawsuit. Any such lawsuit could result in the invalidation of, or render unenforceable, some or all of the relevant patent claims or a finding of non-infringement and the approval of a generic version of RHOFADE sooner than anticipated.

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

If we do not obtain protection under the Hatch-Waxman Act by extending the patent term and obtaining data exclusivity for our products and 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, products, drug candidates and our target indications. Our issued U.S. patent with claims directed to treatment of SK with ESKATA is scheduled to expire in 2022 and our issued U.S. formulation patent with claims directed to high-concentration hydrogen peroxide formulations, including ESKATA and A-101 45% Topical Solution, and methods of use is scheduled to expire in 2035. Certain issued U.S. patents relating to our JAK inhibitors, ATI-501 and ATI-502, are scheduled to expire in 2023 and additional U.S. patents, with claims specifically directed to such JAK inhibitors, are scheduled to expire in 2030. The issued U.S. and Japanese patents licensed from Columbia University relating to the use of certain third party JAK inhibitor for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth, expire in 2031. Our issued U.S. patent covering our lead inhibitors of the MK-2 signaling pathway inhibitor, expires in 2034 and other issued patents covering different MK-2 signaling pathway inhibitors expire in 2031 and 2032. Our issued patents covering our novel inhibitors of ITK expire between 2035 and 2038. Given the amount of time required for the development, testing and regulatory review of new drug candidates, patents protecting 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 extension under the Hatch-Waxman Act for a drug candidate. The Hatch-Waxman Act permits a patent extension term of up to five years beyond the normal expiration of the patent as compensation for patent term lost during development and the FDA regulatory review process, which is limited to the approved indication (or any additional indications approved during the period of extension). However, the total patent term including the period of extension cannot exceed 14 years from the product's approval date. Furthermore, this extension is limited to only one patent per regulatory review period 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. We believe that ESKATA is eligible for patent term extension and we have filed an application with the USPTO requesting patent term extension for one patent that covers ESKATA; however, the USPTO and/or the FDA may disagree with our interpretation.

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 new chemical entity, or NCE, exclusivity for ESKATA, 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 products that are approved for marketing from the products of our competitors. Once we select new trademarks and apply to register them, our trademark

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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 products or drug candidates in order to save costs. We may be forced to abandon or return the rights to specific patents due to a lack of financial resources.

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

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

- others may be able to make formulations or compositions that are the same as or similar to ESKATA, RHOFADE and A-101 45% Topical Solution 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 license and have the right to enforce;
- we, our licensors 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 licensors or any collaborators 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 or exclusively license may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; and

· we may not develop additional proprietary technologies that are patentable.

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

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

Our drug candidates and the activities associated with their development and commercialization, including their design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale and distribution, are subject to comprehensive regulation by the FDA and other regulatory agencies in the United States and by the 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. Other than the approval of ESKATA in the United States, Sweden, United Kingdom, Iceland and Belgium, 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

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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 receive 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 drug candidates in any market.

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

We are seeking marketing approval for ESKATA outside of the United States, and we may also seek marketing approval for RHOFADE or our drug candidates currently in development 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 U.S. Foreign Corrupt Practices Act of 1977, as amended, or the FCPA, 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;
- logistical challenges resulting from distributing ESKATA, RHOFADE or our drug candidates to foreign countries; 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.

ESKATA, RHOFADE or 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.

ESKATA, RHOFADE or 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 FDCA relating to the promotion of prescription drugs may lead to investigations alleging violations of federal and state health care 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 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 health care laws and regulations, which could expose us to significant penalties.

Health care providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any of our drugs and drug candidates for which we obtain marketing approval. Our arrangements with third-party payors, health care professionals and customers may expose us to broadly applicable fraud and abuse and other health care 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 health care 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 health care programs such as Medicare and Medicaid. 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 health care covered business, the Anti-Kickback Statute has been violated. The intent standard was further amended by 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. 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;

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- 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;

- HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any health care benefit program or making false statements relating to health care 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 health care providers, health plans, and health care 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 (commonly known as the Physician Payments Sunshine Act) and its implementing regulations, which requires specified manufacturers of drugs, devices, biologics or 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 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, as well as applicable manufacturers to report annually to CMS ownership and investment interests held by physicians and their immediate family members. 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 health care 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 health care providers; state, local and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other health care providers or marketing expenditures; state laws that require drug manufacturers to report pricing information regarding certain drugs; and/or that require registration of certain employees engaged in marketing activities in the location; 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 health care 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 health care providers, some of whom may recommend, purchase and/or prescribe our products, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other health care 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 health care 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 health care providers or entities with whom we expect to do business is found not to be in compliance with applicable

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laws, it may be subject to criminal, civil or administrative sanctions, including exclusions from participation in government health care programs, which could also materially affect our business.

Recently enacted and future legislation may increase the difficulty and cost for us to obtain marketing approval of our drug candidates and commercialize our products and drug candidates, if approved, 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 health care 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 products or 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 health care systems with the stated goals of containing health care 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. The Affordable Care Act, which was signed into law in March 2010, is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against fraud and abuse, add new transparency requirements for the health care 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 products and 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 health care 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 health care 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 70% 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, as well efforts by the Trump Administration to repeal or replace 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. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision that repealed, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". Additionally, on January

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22, 2018, President Trump signed a continuing resolution on appropriations for fiscal year 2018 that delayed the implementation of certain Affordable Care Act-mandated fees, including the so-called "Cadillac" tax on certain high cost employer-sponsored insurance plans, the annual fee imposed on certain health insurance providers based on market share, and the medical device excise tax on non-exempt medical devices. Further, the Bipartisan Budget Act of 2018, or the BBA, among other things, amended the Affordable Care Act, effective January 1, 2019, to close the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". In July 2018, CMS published a final rule permitting further collections and payments to and from certain Affordable Care Act qualified health plans and health insurance issuers under the Affordable Care Act risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. On December 14, 2018, a Texas U.S. District Court Judge ruled that the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. While the Texas U.S. District Court Judge, as well as the Trump Administration and CMS, has stated that the ruling will have no immediate effect pending appeal of the decision, it is unclear how this decision, subsequent appeals, and other efforts to repeal and replace the Affordable Care Act will impact the Affordable Care Act. We continue to evaluate the impact of the Affordable Care Act and efforts to repeal or replace the Affordable Care Act on our business.

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 that became effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the BBA, will stay in effect through 2027 unless additional Congressional action is taken. The American Taxpayer Relief Act of 2012, which was signed into law in January 2013, 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. Any similar new laws may result in additional reductions in Medicare and other health care funding, which could have a material adverse effect on customers for ESKATA and RHOFADE and, if approved, our drug candidates, and, accordingly, our financial operations.

We expect that the Affordable Care Act, as well as other health care 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 health care 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 has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several recent Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. At the federal level, the Trump Administration's budget proposal for fiscal year 2019 contains further drug price control measures that could be enacted during the 2019 budget process or in other future legislation, including, for example, measures to permit Medicare Part D plans to negotiate the price of certain drugs under Medicare Part B, to allow some states to negotiate drug prices under Medicaid, and to eliminate cost sharing for generic drugs for low-income patients. Further, the Trump Administration released a "Blueprint", or plan, to lower drug prices and reduce

out-of-pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal health care programs, incentivize manufacturers to lower the list price of their drugs, and reduce the out of pocket costs of drug products paid by consumers. HHS has already started the process of soliciting feedback on some of these measures and, at the same time, is immediately implementing others under its existing authority. For example, in September 2018, CMS announced that it will allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2019, and in October 2018, CMS proposed a new rule that would require direct-to-consumer television advertisements of prescription drugs and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that drug or biological product. On January 31, 2019, the HHS Office of Inspector General proposed modifications to the federal Anti-Kickback Statute discount safe harbor for the purpose of reducing the cost of drug products to consumers which, among other things, if finalized, will affect discounts paid by manufacturers to Medicare Part D plans, Medicaid managed care organizations and pharmacy benefit managers working with these organizations. While some of these and other proposed measures may require authorization through additional legislation to become effective, Congress and the Trump Administration have both stated that they will continue to seek new legislative and/or administrative measures to control drug costs. At the state level,

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legislatures have become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain drug access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing 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.

If ESKATA is not granted NCE exclusivity from the FDA, our period of marketing exclusivity for ESKATA will be shorter than previously anticipated, and our business could be harmed.

Under the FDCA, as amended by the Hatch-Waxman Act, a drug that is granted regulatory approval may be eligible for five years of marketing exclusivity in the United States following regulatory approval if that drug is classified as an NCE. A drug can be classified as an NCE if the FDA has not previously approved any other drug containing the same active moiety.

The FDA published a determination on the marketing exclusivity of ESKATA in a cumulative supplement to its Orange Book and determined that ESKATA is eligible for a three-year period of exclusivity for a new product, which would continue until December 14, 2020, rather than the five-year exclusivity for an NCE. While we believe we are entitled to an NCE determination for ESKATA, to date the FDA has not agreed with our position. Although we have appealed the FDA's decision, there can be no assurance that ESKATA will be granted NCE exclusivity, or that the FDA will make a determination on such appeal of their exclusivity decision in a timely manner.

NCE marketing exclusivity, if granted, would preclude approval during the five-year exclusivity period of certain 505(b)(2) applications or ANDAs that rely upon the FDA's findings of safety and efficacy for ESKATA. However, such an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. In this case, we may be afforded the benefit of a 30-month stay against the launch of such a competitive product that would extend from the end of the five-year exclusivity period, and may also be afforded other extensions under applicable regulations, including a judicial extension if applicable requirements are met. If we are not able to gain or exploit the period of marketing exclusivity, we may face significant competitive threats from other manufacturers, including the manufacturers of generic alternatives. Further, even if ESKATA is considered to be an NCE and we are able to gain five-year marketing exclusivity, another company could challenge that decision to seek to overturn the FDA's determination.

ESKATA has been granted three years of new product exclusivity under the Hatch-Waxman Amendments. A three-year period of exclusivity is granted under the Hatch-Waxman Amendments for a drug product that contains an active moiety that has been previously approved when the application contains reports of new clinical investigations (other than bioavailability studies) conducted by the sponsor that were essential to approval of the application. Our

clinical trials of ESKATA were new clinical investigations that were essential to the approval of our NDA. We are entitled to at least three-year exclusivity even if the FDA determines that the hydrogen peroxide moiety was previously approved because our clinical investigations were essential for the approval of our new drug product, ESKATA.

Such three-year exclusivity protection precludes the FDA from approving a marketing application for 505(b)(2) NDA or ANDA for the same conditions of approval as ESKATA for a period of three years from the date of ESKATA's FDA approval, i.e., through December 14, 2020 although the FDA may accept and commence review of such applications during the exclusivity period. This three-year form of exclusivity may also not prevent the FDA from approving an NDA that relies only on its own data to support the change or innovation. Any loss of exclusive marketing rights for ESKATA through introduction of generic or competing products would harm our financial position.

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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 ESKATA 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 products and drug candidates, technology and services in compliance with those laws and regulations, including the U.S. Export Administration Regulations, the International Traffic in Arms Regulations, and economic embargo and trade sanction programs administered by the Treasury Department’s Office of Foreign Assets Control.

U.S. economic sanctions and export control laws and regulations prohibit the shipment of certain products and services to countries, governments and persons targeted by U.S. sanctions. While we are currently taking precautions to prevent doing any business, directly or indirectly, with countries, governments and persons targeted by U.S. sanctions and

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to ensure that our products and drug candidates, 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 products or drug candidates, 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 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, Dr. Stuart Shanler, our Chief Scientific Officer, Dr. David Gordon, our Chief Medical 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 certain of our executive officers, each of them may currently terminate their employment with us or resign at any time. We do not maintain “key person” insurance for any of our key executives other than for Dr. Walker.

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

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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, 2018, we had 169 full-time and part-time employees. As we progress, we expect to experience growth in the number of our employees and the scope of our operations, particularly in the areas of drug development, regulatory affairs, 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 health care 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 health care 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 health care programs, such as Medicare and Medicaid, additional reporting obligations and oversight if we are subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, and the curtailment or restructuring of our operations.

We may not realize the anticipated benefits of our acquisition of Confluence.

In August 2017, we acquired Confluence, including several preclinical drug candidates and Confluence's contract research services business. Acquisitions are inherently risky, and we may not realize the anticipated benefits of the acquisition of Confluence. Specifically, we are subject to the risks that:

- we receive inadequate or unfavorable data from preclinical studies or clinical trials evaluating the acquired preclinical drug candidates;
- we fail to manage the complexities resulting from the larger combined company with distant business locations; and
- we fail to maintain relationships with customers, suppliers and employees.

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

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

The success of our acquisition of RHOFADE will depend, in large part, on our ability to realize operating synergies from combining RHOFADE with our portfolio of drug candidates and ESKATA.

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

- complexities associated with managing an additional commercial-stage drug;
- training our sales force to market both ESKATA and RHOFADE;
- current and prospective employees may experience uncertainty regarding their future roles with our company, which might adversely affect our ability to retain, recruit and motivate key personnel;
- our due diligence processes in connection with the acquisition may fail to identify significant problems, risks, liabilities or other shortcomings or challenges associated with the RHOFADE assets, including problems, risks, liabilities or other shortcomings or challenges with respect to intellectual property, product quality and safety and other known and unknown liabilities; and
- performance shortfalls as a result of the diversion of management’s attention caused by completing the acquisition and integrating RHOFADE.

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

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 ESKATA, RHOFADE or any drug candidate;
- changes in financial estimates by us or by any securities analysts who might cover our stock;

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- conditions or trends in our industry;
- changes in the structure of health care payment systems;
- 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.

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.

Sales of a substantial number of shares of our common stock into the market 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

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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.

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.

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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 $1.07 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.

We also qualify as a “smaller reporting company” as defined in Rule 12b-2 of the Exchange Act, and so long as we remain a smaller reporting company, we benefit from some of the same scaled disclosure requirements.

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.

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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, 2018, we had federal and state net operating loss carryforwards of $199.5 million and $212.4 million, respectively, which will begin to expire in 2032. As of December 31, 2018, we also had federal research and development tax credit carryforwards of $4.9 million which begin to expire in 2032, and state research and development tax credit carryforwards of $0.1 million which begin to expire in 2022. 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 completed an analysis under Section 382 for net operating loss carryforwards generated from July 13, 2012 through December 31, 2016. Although we have experienced Section 382 ownership changes since 2012, we have concluded that we should have sufficient ability to utilize net operating loss carryforwards accumulated during the periods tested. We have not yet determined if a Section 382 ownership change has occurred during the year ended December 31, 2017, or for Confluence prior to the acquisition. 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.

The 2017 comprehensive tax reform bill could adversely affect our business and financial condition.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017 was signed into law which significantly revised the Internal Revenue Code of 1986, as amended. The federal income tax legislation, among other things, contained significant changes to corporate taxation, including reduction of the corporate tax rate from a top marginal rate of 35% to a flat rate of 21%, limitation of the tax deduction for interest expense to 30% of adjusted earnings (except for certain small businesses), limitation of the deduction for net operating losses to 80% of current year taxable income and elimination of net operating loss carrybacks, one time taxation of offshore earnings at reduced rates regardless of whether they are repatriated, elimination of U.S. tax on foreign earnings (subject to certain important exceptions), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the changes to the federal tax law is uncertain and our business and financial condition could be adversely affected. In addition, it is uncertain how various states will respond to the changes in the federal tax law. The impact of this tax reform on holders of our common stock is also uncertain and could be adverse. We

urge our stockholders to consult with their legal and tax advisors with respect to this legislation and the potential tax consequences of investing in or holding our common stock.

We have broad discretion in the use of proceeds from our equity financing transactions 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 equity financing transactions over the last several years. 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 transactions to conduct commercial activities for ESKATA and RHOFADE, and to fund the continued research and development of our drug candidates, as well as 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 these net proceeds.

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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 our current loan agreement with Oxford prohibits us, and future debt agreements may also 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.

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Item 2. Properties

We currently sublease 33,019 square feet of space for our headquarters in Wayne, Pennsylvania. Subject to the consent of Chesterbrook Partners, LP, the Landlord, as set forth in the lease by and between them and Auxilium Pharmaceuticals, LLC, the Sublandlord, the term of our sublease has a term through October 2023. If for any reason the lease between the Landlord and Sublandlord is terminated or expires prior to October 2023, our sublease will automatically terminate. We also lease 21,056 square feet of office and laboratory space in St. Louis, Missouri, which has a term of 10 years which we expect to commence by the end of the first half of 2019. Until we move to that space, we continue to occupy 3,689 square feet of office and laboratory space in St. Louis, Missouri under the terms of a short-term lease. We believe that our facilities are suitable and adequate to meet our current needs.

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 is listed on the Nasdaq Global Select Market under the symbol "ACRS."

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 15, 2019, we had 41,269,643 shares of common stock outstanding held by 71 holders of record. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Recent Sales of Unregistered Securities

On November 29, 2018, we issued 253,208 shares of our common stock upon the achievement of a specified development milestone in accordance with the terms of the Confluence Agreement to former Confluence equity holders who are "accredited investors," as that term is defined in the Securities Act, in reliance on the exemption from registration afforded by Section 4(a)(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or "blue sky" laws. Each of the former Confluence equity

holders who received such shares of our common stock has represented that it was acquiring such shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof. Such shares have not been registered under the Securities Act and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the Securities Act and any applicable state securities laws.

Purchases of Equity Securities by the Issuer and Affiliated Parties

None.

Item 6. Selected Consolidated Financial Data

Not applicable.

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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 physician-led biopharmaceutical company focused on dermatological and immuno-inflammatory diseases. We have two commercial products and a diverse pipeline of drug candidates.

Our first commercial product, ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, is a proprietary formulation of high-concentration hydrogen peroxide topical solution which was approved by the U.S. Food and Drug Administration, or FDA, in December 2017 as an office-based prescription treatment for raised seborrheic keratosis, or SK, a common non-malignant skin tumor. We launched ESKATA in the United States in May 2018. We also submitted a Marketing Authorization Application, or MAA, for ESKATA in select countries in the European Union, Norway and Iceland in July 2017 using a decentralized procedure. In February 2019, we received approval from the Swedish Medical Products Agency to market ESKATA (hydrogen peroxide) cutaneous solution, 685 mg for the treatment in adults of SKs that are not pedunculated and have up to a maximum diameter of 15 millimeters each. We have also received approval to market ESKATA in the United Kingdom, Iceland and Belgium.

In November 2018, we acquired RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan Sales, LLC, or Allergan. RHOFADE was approved by the FDA in January 2017 for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults. Persistent facial redness is the most common sign of rosacea in most skin types.

We continue to develop our sales, marketing and product distribution capabilities for ESKATA and RHOFADE in order to support our commercialization efforts in the United States. We plan to continue to deploy sales representatives in approximately 50 territories in the United States which we believe will allow us to reach the health care providers in the United States with the highest potential for prescribing ESKATA and RHOFADE to their patients.

We are also developing another high-concentration formulation of hydrogen peroxide, A-101 45% Topical Solution, as a prescription treatment for common warts, also known as verruca vulgaris. On an annual basis, approximately 2.0 million people in the United States are diagnosed with common warts.

Additionally, in 2015, we in-licensed exclusive, worldwide rights from Rigel Pharmaceuticals, Inc., or Rigel, to certain inhibitors of the Janus kinase, or JAK, family of enzymes, for specified dermatological conditions, including alopecia areata, or 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, or AT, and total hair loss on the scalp and body, known as alopecia universalis, or AU. We are also developing these JAK inhibitors for the treatment of vitiligo, androgenetic alopecia, or AGA, also known as male or female pattern baldness, and atopic dermatitis.

In 2016, in connection with the acquisition of Vixen Pharmaceuticals, Inc., or Vixen, 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 biopharmaceutical company.

In 2017, we acquired Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or Confluence. The acquisition of Confluence added small molecule drug discovery and preclinical development capabilities that allowed us to bring early-stage research and development activities in-house that we previously outsourced to third parties. We intend to leverage the proprietary KINect drug discovery platform to identify potential drug candidates that we may

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develop independently or with partners. We also acquired several preclinical drug candidates, including additional topical JAK inhibitors known as soft-JAK inhibitors, inhibitors of the MK-2 signaling pathway and inhibitors of interleukin-2-inducible T cell kinase, or ITK. Soft-JAK inhibitors may be topically applied and active in the skin, but will be rapidly metabolized and inactivated when they enter the bloodstream, which may result in significantly reduced systemic exposure. We also earn revenue from Confluence's provision of contract research services to third parties.

Since our inception, we have incurred significant operating losses. Our net loss was $132.7 million for the year ended December 31, 2018 and $68.5 million for the year ended December 31, 2017. As of December 31, 2018, we had an accumulated deficit of $292.2 million. We expect to incur significant expenses and operating losses related to product manufacturing, marketing, sales and distribution over the next several years as we continue to commercialize ESKATA and RHOFADE. In addition, ESKATA and RHOFADE, and our drug candidates if approved, may not achieve commercial success. We also 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. 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. We may also incur expenses in connection with the in-license or acquisition of additional drug candidates. Furthermore, we have incurred and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses. As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy.

We have historically financed our operations primarily with sales of our convertible preferred stock, as well as net proceeds from our initial public offering, or IPO, in October 2015, subsequent public offerings, and a private placement of our common stock. 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 products or drug candidates or delay our pursuit of potential in-licenses or acquisitions.

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, ATI-501 and ATI-502, or the Rigel License Agreement. Under this agreement, we intend to develop these JAK inhibitors for the treatment of AA and 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 Rigel License 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 Rigel License 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 Rigel License 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 Rigel License 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.

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

In March 2016, we entered into a stock purchase agreement, or the Vixen Agreement, with Vixen, and JAK1, LLC, JAK2, LLC and JAK3, LLC, or together, the Selling Stockholders, and Shareholder Representative Services LLC 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 through March 2022, with such amounts being creditable against specified future payments that may be paid under the Vixen Agreement.

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 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, as amended, the Columbia License Agreement. Under the Columbia 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 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. 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.

Agreement and Plan of Merger with Confluence

In August 2017, we entered into an Agreement and Plan of Merger, or the Confluence Agreement, with Confluence, Aclaris Life Sciences, Inc., our wholly-owned subsidiary, or Merger Sub, and Fortis Advisors LLC, as representative of the equity holders of Confluence. Pursuant to the terms of the Confluence Agreement, the Merger Sub merged with and into Confluence, with Confluence surviving as our wholly-owned subsidiary. We paid $10.3 million in cash and issued 349,527 shares of our common stock with a fair value of $9.7 million to the Confluence equity holders.

In November 2018, we achieved a development milestone specified in the Confluence Agreement. The milestone payment to the former Confluence equity holders was comprised of $2.5 million in cash and 253,208 shares of our common stock with a fair value of $2.2 million. We also agreed to pay the former Confluence equity holders aggregate additional contingent consideration of up to $75.0 million, based upon the achievement of certain regulatory and commercial milestones set forth in the Confluence Agreement. In addition, we have agreed to pay the former Confluence equity holders specified future royalty payments calculated as a 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. In addition, if we sell, license or transfer any of the intellectual property acquired from Confluence pursuant to the Confluence Agreement to a third party, we will be obligated to pay the former

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Confluence equity holders a portion of any incremental consideration (in excess of the development and milestone payments described above) that we receive from such sale, license or transfer in specified circumstances.

License, Development and Commercialization Agreement with Cipher Pharmaceuticals Inc.

In April 2018, we entered into an exclusive license agreement with Cipher Pharmaceuticals Inc., or Cipher, for the rights to obtain regulatory approval of and commercialize A-101 40% Topical Solution, which we market under the brand name ESKATA in the United States, in Canada for the treatment of SK, or the Cipher License Agreement. Under the Cipher License Agreement, Cipher is responsible for obtaining marketing approval in Canada for A-101 40% Topical Solution. We will supply Cipher with finished product, and, if regulatory approval is obtained, Cipher will be responsible for distribution and commercialization of A-101 40% Topical Solution in Canada. Additionally, Cipher is responsible for all expenses related to regulatory and commercial activities for A-101 40% Topical Solution in Canada. We received an upfront payment of $1.0 million upon signing of the Cipher License Agreement and $0.5 million upon the achievement of a specified regulatory milestone. Pursuant to the Cipher License Agreement, we can earn a remaining payment of $0.5 million upon the achievement of a specified regulatory milestone, and aggregate payments of $1.75 million upon the achievement of specified commercial milestones. Cipher will also be required to pay us a low double-digit percentage royalty on net sales of A-101 40% Topical Solution in Canada. The term of the Cipher License Agreement expires on the later of the expiration of applicable patents in Canada or the 15th anniversary of the first commercial sale of licensed product in Canada. Cipher submitted a New Drug Submission for A-101 40% Topical Solution for the treatment of raised SKs, which was accepted for review by Health Canada in December 2018.

Asset Purchase Agreement with Allergan

In November 2018, we completed the acquisition of RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan, pursuant to the Asset Purchase Agreement dated as of October 15, 2018, or as amended, the Asset Purchase Agreement.

At the closing of the acquisition, we paid total cash consideration of $66.1 million, consisting of $59.6 million paid to Allergan and $6.5 million placed in escrow. We have also agreed to pay Allergan a one-time payment of $5.0 million upon the achievement of a specified development milestone related to the potential development of an additional dermatology product. In addition, we have agreed to pay Allergan specified royalty payments, ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to a particular product, such as RHOFADE, have expired or, if later, November 30, 2028. In addition, we have agreed to assume the obligation to pay

specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Members of our management team, including Neal Walker, Frank Ruffo, Christopher Powala and Stuart Shanler, as well as Stephen Tullman, the chairman of our board of directors, are former stockholders of Vicept Therapeutics, Inc., and Dr. Shanler is also a current member of Aspect Pharmaceuticals, LLC. In their capacities as current or former holders of equity interests in these entities, these individuals may be entitled to receive a portion of the potential future payments payable by us. We incurred an aggregate expense of approximately $0.2 million and $0 related to royalty payments under these agreements during the years ended December 31, 2018 and 2017, respectively.

RHOFADE was approved by the FDA in January 2017 for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults, and the product became commercially available in the United States in May 2017.

Other Third-Party Agreements

Under an assignment agreement, pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of ESKATA, or other related products, at rates ranging in low single-digit percentages of net sales, as defined in the agreement. Under this assignment agreement, we paid $0.2 million in connection with a specified development milestone, and there are no remaining milestone payment obligations.

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In connection with the assignment agreement, we also entered into a finder's services agreement under which we have made aggregate milestone payments of $3.0 million upon the achievement of specified pre-commercialization milestones, such as clinical trials and regulatory approvals, and commercial milestones as described in the agreement. We have also agreed to make an additional payment of $3.0 million upon the achievement of a specified commercial milestone. In addition, we have agreed to pay royalties on sales of ESKATA, or other related products, at a low single-digit percentage of net sales, as defined in the agreement.

Components of Our Results of Operations

Revenue

Product Sales

We promote ESKATA and RHOFADE through our sales force which we believe will allow us to reach the health care providers in the United States with the highest potential for prescribing ESKATA and RHOFADE to their patients.

We sell ESKATA to one wholesaler, McKesson Specialty Care Distribution, or McKesson, which in turn resells ESKATA to health care providers. We have also entered into agreements with two group purchasing organizations, or GPOs, and may enter into additional agreements with other GPOs and corporate accounts that provide for administrative fees and discounted pricing in the form of volume-based rebates and chargebacks. We have no sales of ESKATA in countries outside of the United States.

We began commercializing RHOFADE in the United States in December 2018. We currently rely on Allergan to distribute RHOFADE on our behalf pursuant to the terms of a transition services agreement while we develop our sales, marketing and distribution capabilities to support the commercialization of RHOFADE in the United States. We sell RHOFADE to wholesalers in the United States, which, in turn, distribute it to pharmacies that will ultimately fill patient prescriptions. We may also enter into arrangements with health care providers, pharmacy benefit managers, third-party payors, and GPOs which provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts, with respect to the purchase of RHOFADE. We have no sales of RHOFADE in countries outside of the United States.

Contract Research

We earn revenue from the provision of laboratory services to clients through Confluence, our wholly-owned subsidiary. Contract research revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis and are generally billed on a monthly basis in arrears for services rendered.

We have also received revenue from grants under the Small Business Innovation Research program of the National Institutes of Health, or NIH. During the year ended December 31, 2018, we had two active grants from NIH related to early-stage research. As of December 31, 2018, there were no remaining funds available to us under the grants.

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Cost of Revenue

Cost of revenue consists of the cost of manufacturing the finished product forms of ESKATA and RHOFADE, as well as costs incurred in connection with the provision of contract research services to our clients through Confluence. Cost of revenue primarily includes:

Product sales:

- third-party cost of manufacturing and assembly of finished product forms of ESKATA and RHOFADE;
- depreciation of manufacturing equipment;
- product release and stability testing;
- warehousing and insurance costs;
- transition service costs payable to Allergan;
- royalty payments;
- Prescription Drug User Fee Act, or PDUFA, fees;
- non-cash charge to adjust the carrying-value of inventory to net realizable value;
    - non-cash charge related to the fair value step-up of acquired RHOFADE inventory; and
- non-cash amortization of the intangible asset related to RHOFADE intellectual property.

Contract research:

- employee-related expenses, which include salaries, benefits and stock-based compensation;
- outsourced professional scientific services;
- depreciation of laboratory equipment;
- facility-related costs; and
- laboratory materials and supplies used to support the services provided.

Research and Development Expenses

Research and development expenses consist of expenses incurred in connection with the discovery and development of our drug candidates. These expenses primarily 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;
- medical affairs-related expenses;
- 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;
- laboratory materials and supplies used to support our research activities; and
- non-cash charges for changes in the fair value of contingent consideration related to the acquisition of Confluence.

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 clinical trials of A-101 45% Topical Solution for the treatment of common warts, and conduct clinical trials and prepare regulatory filings for our other drug candidates. We expense research and development costs as incurred. Our direct research and development expenses primarily consist of external costs including fees paid to CROs, consultants, investigator sites, regulatory agencies and third parties that manufacture our preclinical and clinical trial materials, and are

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tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses, to specific research and development programs.

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 subjects receive;
- the duration of subject 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.

Sales and Marketing Expenses

Sales and marketing expenses include salaries and related costs for our field sales force, as well as personnel in our marketing and sales operations functions, including stock-based compensation, travel expenses, expenses related to leasing a fleet of vehicles for our field-based sales force, and recruiting expenses. Sales and marketing expenses also include costs of content development, advertising, sponsorships and attendance at dermatology conferences, and costs incurred under the transition services agreement with Allergan.

Additionally, we anticipate incurring significant sales and marketing expenses as we continue to commercialize ESKATA and RHOFADE in the United States.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs for personnel in executive, administrative, finance, investor relations and legal functions, including stock-based compensation, travel expenses and recruiting expenses. General and administrative expenses also include facility-related costs, patent filing and prosecution costs, professional fees for legal, auditing and tax services, insurance costs, costs incurred under the transition services agreement with Allergan, as well as payments made under a terminated related party sublease agreement and milestone payments under our finder's services agreement. We anticipate that our general and administrative expenses will continue to 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.

Other Income, net

Other income, net consists of interest earned on our cash, cash equivalents and marketable securities, interest expense, and gains and losses on transactions denominated in foreign currencies.

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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. 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.

Revenue Recognition

We account for revenue in accordance with Accounting Standards Codification, or ASC, Topic 606, Revenue from Contracts with Customers. Under ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration to which we expect to be entitled in exchange for those goods or services.

To determine revenue recognition in accordance with ASC Topic 606, we perform the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) performance obligations are satisfied. We recognize revenue when collection of the consideration we are entitled to under a contract with a customer is probable. At contract inception, we assess the goods or services promised within a contract with a customer to identify the performance obligations, and to determine if they are distinct. We recognize revenue that is allocated to each distinct performance obligation when (or as) that performance obligation is satisfied.

Product Sales, net

We recognize revenue from product sales at the point the customer obtains control, which generally occurs upon delivery, and also include estimates of variable consideration in the same period revenue is recognized. Components of variable consideration include trade discounts and allowances, product returns, government rebates, discounts and rebates, other incentives such as patient co-pay assistance, and other fee for service amounts. Variable consideration is recorded on the consolidated balance sheet as either a reduction of accounts receivable, if payable to a customer, or as a current liability, if payable to a third-party other than a customer. We consider all relevant information when estimating variable consideration such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of net revenue we can recognize is constrained by estimates of variable consideration which are included in the transaction price. Payment terms with customers do not exceed one year and, therefore, we do not account for a financing component in our arrangements. We expense incremental costs of obtaining a contract with a customer, including sales commissions, when incurred as the period of benefit is less than one year. Shipping and handling costs for product shipments to customers are recorded as sales and marketing expenses in the consolidated statement of operations.

Trade Discounts and Allowances - We may provide customers with trade discounts, rebates, allowances or other incentives. We record an estimate for these items as a reduction of revenue in the same period the revenue is recognized.

Government and Payor Rebates – We may contract with certain third-party payors, primarily health insurance companies, pharmacy benefit managers and government programs, for the payment of rebates with respect to utilization of our products. We also have agreements with GPOs that provide for administrative fees and discounted pricing in the form of volume-based rebates. We are also subject to discount obligations under state Medicaid programs and Medicare. We record an estimate for these rebates as a reduction of revenue in the same period the revenue is recognized.

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Other Incentives - Other incentives includes our co-pay assistance program which is intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by payors. We estimate and record an accrual for these incentives as a reduction of revenue in the period the revenue is recognized. Our estimated amounts for co-pay assistance are based upon the number of claims and the cost per claim that we expect to receive associated with product that has been sold to customers but remains in the distribution channel at the end of each reporting period.

Product Returns - Consistent with industry practice, we have a product returns policy which may provide customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The right of return lapses upon shipment of the goods to a patient. We record an estimate for the amount of product which may be returned as a reduction of revenue in the period the related revenue is recognized. Our estimates for product returns are based upon available industry data and our own sales information, including visibility into the inventory remaining in the distribution channel. There is no returns liability associated with sales of ESKATA as we have a no returns policy for ESKATA.

Contract Research

Revenue related to laboratory services is generally recognized as the laboratory services are performed, based upon the rates specified in the contracts. Under ASC Topic 606, we elected to apply the "right to invoice" practical expedient when recognizing contract research revenue. We recognize contract research revenue in the amount to which we have the right to invoice.

We recognize revenue related to grants as amounts become reimbursable under each grant, which is generally when research is performed, and the related costs are incurred.

Other Revenue

Licenses of Intellectual Property – We recognize revenue received from non-refundable, upfront fees related to the licensing of intellectual property when the intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the license has been transferred to the customer, and the customer is able to use and benefit from the license.

Milestone Payments - At the inception of each arrangement that includes milestone payments, we evaluate whether the milestones are considered probable of being reached and estimate the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the

associated milestone value is included in the amount allocated to the license of intellectual property. Milestone payments that are not within our control or the control of the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

Inventory

Inventory includes the third-party cost of manufacturing and assembly of the finished product forms of ESKATA and RHOFADE, quality control and other overhead costs. Inventory is stated at the lower of cost or net realizable value. Inventory is adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon assumptions about future demand and market conditions. Our inventory is comprised primarily of finished goods.

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Intangible Assets

Our intangible assets include both finite-lived and indefinite-lived assets. Finite-lived intangible assets are amortized over their estimated useful life based on the pattern over which the intangible assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the straight-line method of amortization is used. Our finite-lived intangible assets consist of a research technology platform acquired through the acquisition of Confluence and the intellectual property rights related to RHOFADE. Our indefinite-lived intangible assets consist of an in-process research and development, or IPR&D, drug candidate acquired through the acquisition of Confluence. IPR&D assets are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. The cost of IPR&D assets is either amortized over their estimated useful life beginning when the underlying drug candidate is approved and launched commercially, or expensed immediately if development of the drug candidate is abandoned.

Finite-lived intangible assets are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment at least annually, which we perform during the fourth quarter, or when indicators of an impairment are present. We recognize an impairment loss when and to the extent that the estimated fair value of an indefinite-lived intangible asset is less than its carrying value.

Goodwill

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which we perform during the fourth quarter, or when indicators of an impairment are present. We consider each of our operating segments, dermatology therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. We have attributed the full amount of the goodwill in connection with the acquisition of Confluence, or $18.5 million, to our dermatology therapeutics segment. We perform an impairment test annually which is a qualitative assessment based upon current facts and circumstances related to operations of the dermatology therapeutics segment. If our qualitative assessment indicates an impairment may be present, we would perform the required quantitative analysis and an impairment charge would be recognized to the extent that the estimated fair value of the reporting unit is less than its carrying amount. However, any loss recognized would not exceed the total amount of goodwill allocated to that reporting unit.

Contingent Consideration

We initially recorded the contingent consideration related to future potential payments based upon the achievement of specified development, regulatory and commercial milestones, resulting from the acquisition of Confluence, at its estimated fair value on the date of acquisition. Changes in fair value reflect new information about the likelihood of

the payment of the contingent consideration and the passage of time. For example, if the timing of the development of an acquired drug candidate, or the size of potential commercial opportunities related to an acquired drug, differ from our assumptions, then the fair value of contingent consideration would be adjusted accordingly. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in our consolidated statement of operations.

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

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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.

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 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.

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Results of Operations

Comparison of Years Ended December 31, 2018 and 2017

	Year Ended December 31,		
	2018	2017	Change
	(In thousands)		
Revenues:			
Product sales, net	$ 3,940	$ —	$ 3,940
Contract research	4,651	1,683	2,968
Other revenue	1,500	—	1,500
Total revenue, net	10,091	1,683	8,408
Cost of revenue	6,850	1,207	5,643
Gross profit	3,241	476	2,765
Operating expenses:			
Research and development	63,009	39,790	23,219
Sales and marketing	47,997	13,769	34,228
General and administrative	27,649	19,340	8,309
Total operating expenses	138,655	72,899	65,756
Loss from operations	(135,414)	(72,423)	(62,991)
Other income, net	2,676	2,070	606
Loss before income taxes	(132,738)	(70,353)	(62,385)
Provision for (benefit from) income taxes	—	(1,830)	1,830
Net loss	$ (132,738)	$ (68,523)	$ (64,215)

Revenue

Revenue was $10.1 million for the year ended December 31, 2018, compared to $1.7 million for the year ended December 31, 2017. Product sales, net included $2.8 million and $1.1 million of net revenue from sales of ESKATA and RHOFADE, respectively, during the year ended December 31, 2018. We acquired RHOFADE in November 2018. Contract research revenue of $4.7 million and $1.7 million for the years ended December 31, 2018 and 2017, respectively, was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017. Other revenue was related to the Cipher License Agreement and consisted of an upfront payment of $1.0 million and $0.5 million earned upon the achievement of a specified regulatory milestone.

Cost of Revenue

Cost of revenue was $6.9 million for the year ended December 31, 2018 and was comprised of $1.5 million and $1.0 million of costs related to ESKATA and RHOFADE product sales, net, respectively. Cost of revenue included $0.6 million of non-cash amortization related to the intangible asset for the RHOFADE intellectual property rights, and a non-cash charge of $1.1 million related to the write-down of ESKATA finished inventory. We also incurred $4.3 million of costs related to providing laboratory services to our clients through Confluence. Cost of revenue was $1.2 million for the year ended December 31, 2017 and was comprised entirely of costs incurred to provide laboratory services to our clients through Confluence, which we acquired in August 2017.

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Research and Development Expenses

The following table summarizes our research and development expenses:

	Year Ended December 31,		
	2018	2017	Change
	(In thousands)		
ESKATA	$ 2,574	$ 6,031	$ (3,457)
A-101 45% Topical Solution	10,114	4,681	5,433
JAK inhibitors	22,457	11,789	10,668
Personnel expenses	8,332	6,131	2,201
Change in contingent consideration	1,272	—	1,272
Other research and development expenses	11,780	5,687	6,093
Stock-based compensation	6,480	5,471	1,009
Total research and development expenses	$ 63,009	$ 39,790	$ 23,219

The decrease in expenses associated with the development of ESKATA resulted primarily from the filing of our NDA in February 2017 following the completion of clinical trials. Expenses related to A-101 45% Topical Solution increased primarily due to the initiation of our Phase 3 clinical trials for the treatment of common warts during the third quarter of 2018. Development expenses for our JAK inhibitors increased due to continued growth in both preclinical and clinical trial expenses as we continue to conduct multiple Phase 2 clinical trials of ATI-501 and ATI-502. The increase in personnel expenses was primarily the result of increased headcount. The increase in stock-based compensation expense was primarily the result of new awards granted during 2018. The change in contingent consideration was the result of updates to our assumptions related to our soft-JAK inhibitors that reflected the achievement of a specified development milestone in November 2018 under the Confluence Agreement. Other research and development expenses primarily included expenses for medical affairs activities related to ESKATA, and expenses related to drug discovery performed by Confluence, which we acquired in August 2017; we did not incur similar drug discovery expenses prior to that acquisition. The increase in other research and development expenses was also driven by preclinical development of ATI-450, our MK-2 inhibitor, and research expenses related to our ITK inhibitor.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Year Ended December 31,		
	2018	2017	Change
	(In thousands)		
Direct marketing and professional fees	$ 20,683	$ 7,576	$ 13,107
Personnel expenses	14,680	2,817	11,863
Other sales and marketing expenses	9,142	1,525	7,617
Stock-based compensation	3,492	1,851	1,641
Total sales and marketing expenses	$ 47,997	$ 13,769	$ 34,228

Direct marketing and professional fees, as well as other sales and marketing expenses, increased as a result of the commercial launch of ESKATA, which occurred in May 2018. Personnel and stock-based compensation expenses have increased due to increased headcount, including the hiring of our field sales force during the year ended December 31, 2018. Other sales and marketing expenses included sales operations, travel costs, depreciation and other miscellaneous expenses. Other sales and marketing expenses included costs related to our national launch meeting, employee training, samples fulfillment and expenses related to leasing a fleet of vehicles. The increase in other sales and marketing expenses was primarily related to onboarding our field sales force during the year ended December 31, 2018.

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General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Year Ended December 31,		
	2018	2017	Change
	(In thousands)		
Personnel expenses	$ 7,006	$ 4,378	$ 2,628
Professional and legal fees	5,649	4,023	1,626
Facility and support services	2,349	1,941	408
Milestone payment	1,500	1,000	500
Other general and administrative expenses	1,828	1,101	727
Stock-based compensation	9,317	6,897	2,420
Total general and administrative expenses	$ 27,649	$ 19,340	$ 8,309

Personnel and stock-based compensation expenses have increased due to increased headcount as we expanded our operations. Professional and legal fees included accounting, legal and investor relations costs associated with being a public company, as well as legal fees related to patents. The increase in professional and legal fees was related to legal and consulting expenses incurred as a result of the commercial launch of ESKATA in May 2018, as well as fees associated with business development activities. The milestone payment of $1.5 million in the year ended December 31, 2018 was made upon the achievement of specified commercial milestones under our Finder's Services Agreement with KPT Consulting, LLC. The milestone payment of $1.0 million in the year ended December 31, 2017 was made upon the achievement of specified regulatory milestones pursuant to our Finder's Services Agreement with KPT Consulting, LLC. Facility and support services included general office expenses and information technology costs which have risen due to our increased headcount as well as the relocation of our headquarters during the year ended December 31, 2018. Other general and administrative expenses included insurance, travel costs, depreciation and other miscellaneous expenses.

Other Income, net

The $0.6 million increase in other income, net was primarily due to higher invested balances of marketable securities as a result of funds received from our financing transactions in 2017 and 2018, as well as higher yields on those invested balances.

Provision for (Benefit from) Income Taxes

Provision for income taxes was a net benefit of $1.8 million for the year ended December 31, 2017 and was comprised primarily of the revaluation of our deferred tax assets, net resulting from the Tax Cuts and Jobs Act of 2017 which was enacted on December 22, 2017.

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Comparison of Years Ended December 31, 2017 and 2016

	Year Ended December 31,		
	2017	2016	Change
	(In thousands)		
Contract research	$ 1,683	$ —	$ 1,683
Cost of revenue	1,207	—	1,207
Gross profit	476	—	476
Operating expenses:			
Research and development	39,790	33,476	6,314
Sales and marketing	13,769	3,295	10,474
General and administrative	19,340	11,796	7,544
Total operating expenses	72,899	48,567	24,332
Loss from operations	(72,423)	(48,567)	(23,856)
Other income, net	2,070	488	1,582
Loss before income taxes	(70,353)	(48,079)	(22,274)
Provision for (benefit from) income taxes	(1,830)	—	(1,830)
Net loss	$ (68,523)	$ (48,079)	$ (20,444)

Revenue

Revenue was $1.7 million for the year ended December 31, 2017, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017. We did not generate any revenue in the year ended December 31, 2016.

Cost of Revenue

Cost of revenue was $1.2 million for the year ended December 31, 2017, and was comprised entirely of costs incurred to provide laboratory services to our clients through Confluence, which we acquired in August 2017. We did not incur any cost of revenue in the year ended December 31, 2016.

Research and Development Expenses

The following table summarizes our research and development expenses:

	Year Ended December 31,		
	2017	2016	Change
	(In thousands)		
ESKATA	$ 6,031	$ 14,257	$ (8,226)
A-101 45% Topical Solution	4,681	1,100	3,581
JAK inhibitors	11,789	7,313	4,476
Personnel expenses	6,131	3,728	2,403
Acquisition of Vixen	—	3,435	(3,435)
Other research and development expenses	5,687	1,352	4,335
Stock-based compensation	5,471	2,291	3,180
Total research and development expenses	$ 39,790	$ 33,476	$ 6,314

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The increase of $6.3 million in research and development was primarily driven by an increase of $3.6 million of expenses related to our Phase 2 clinical trials of A-101 45% Topical Solution, an increase of $4.5 million in preclinical and clinical trial development expenses related to our JAK inhibitor technology, increases of $2.4 million in payroll-related expenses and $3.2 million in stock-based compensation expense, both of which were due to higher headcount, and a $2.9 million increase in expenses related to medical affairs activities. We also incurred $1.0 million of expenses related to drug discovery research performed by Confluence in the year ended December 31, 2017. The increases noted above were partially offset by a $8.2 million decrease in costs associated with the development of ESKATA as a result of the completion of our Phase 3 clinical trials in November 2016, and $3.4 million in expenses associated with the acquisition of Vixen in the year ended December 31, 2016, for which there was no similar transaction in 2017.

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Year Ended December 31,		
	2017	2016	Change
	(In thousands)		
Direct marketing and professional fees	$ 7,576	$ 2,195	$ 5,381
Personnel expenses	2,817	999	1,818
Other sales and marketing expenses	1,525	101	1,424
Stock-based compensation	1,851	—	1,851
Total research and development expenses	$ 13,769	$ 3,295	$ 10,474

The increase in direct marketing and professional fees was primarily attributable to $5.2 million in market research expenses related to pre-commercial launch activities for ESKATA. Personnel and stock-based compensation expenses increased due to increased headcount, including the hiring of regional sales managers and sales operations employees during the year ended December 31, 2017. Other sales and marketing expenses included sales operations, travel costs, depreciation and other miscellaneous expenses and increased primarily as a result of pre-commercial launch activities for ESKATA.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Year Ended December 31,		
	2017	2016	Change
	(In thousands)		
Personnel expenses	$ 4,378	$ 3,230	$ 1,148
Professional and legal fees	4,023	2,740	1,283
Facility and support services	1,941	858	1,083
Milestone payment	1,000	300	700
Other general and administrative expenses	1,101	855	246
Stock-based compensation	6,897	3,813	3,084
Total general and administrative expenses	$ 19,340	$ 11,796	$ 7,544

Personnel and stock-based compensation expenses increased due to increased headcount. Professional and legal fees included accounting, legal and investor relations costs associated with being a public company, as well as legal fees related to patents. The increase in professional and legal fees primarily related to legal and consulting expenses incurred in conjunction with our acquisition of Confluence, for which there were no similar amounts in 2016, and legal fees related to patents. Facilities and support services included a one-time charge to rent expense of $0.5 million in connection with the early termination of our sublease with NST Consulting, LLC. In addition, milestone payments pursuant to the Finder's Services Agreement related to ESKATA increased by $0.7 million in 2017 compared to 2016.

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Other Income, net

The $1.6 million increase in other income, net was primarily due to higher invested balances of marketable securities as a result of funds received from our financing transactions in 2016 and 2017.

Provision for (Benefit from) Income Taxes

Provision for income taxes was a net benefit of $1.8 million for the year ended December 31, 2017 and was comprised primarily of the revaluation of our deferred tax assets, net resulting from the Tax Cuts and Jobs Act of 2017 which was enacted on December 22, 2017.

Liquidity and Capital Resources

Since our inception, we have incurred net losses and negative cash flows from our operations. Prior to our acquisition of Confluence in August 2017, we did not generate any revenue. We have financed our operations over the last several years primarily through sales of our equity securities in public offerings and a private placement transaction. As described below, in October 2018 we also entered into a loan facility with an institutional lender.

As of December 31, 2018, we had cash, cash equivalents and marketable securities of $168.0 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 recent debt financing obligation, sublease obligations, capital lease obligations and contingent obligations under acquisition and intellectual property licensing agreements, which are summarized below under “Contractual Obligations and Commitments.”

Private Placement

In June 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.

November 2016 Public Offering

In November 2016, we closed a 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.

At-The-Market Facility

In November 2016, we entered into a sales agreement with Cowen and Company, LLC, or Cowen, pursuant to which Cowen acted as our agent in connection with sales of our common stock from time to time under an “at-the-market” equity facility. In April 2017, we sold 635,000 shares of our common stock at a weighted average price per share of $31.50, for aggregate gross proceeds of approximately $20.0 million. We paid underwriting discounts and commissions of $0.6 million, and we also incurred expenses of $0.1 million in connection with this sale. In October 2018, we terminated the at-the-market sales agreement with Cowen without having sold any additional shares of common stock.

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August 2017 Public Offering

In August 2017, we closed our follow-on public offering in which we sold 3,747,602 shares of common stock at a price to the public of $23.02 per share, for aggregate gross proceeds of $86.3 million. We paid underwriting discounts and commissions of $5.2 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 $80.9 million.

October 2018 Public Offering

In October 2018, we closed a public offering in which we sold 9,941,750 shares of common stock at a price to the public of $10.75 per share, for aggregate gross proceeds of $106.9 million. We paid underwriting discounts and commissions of $6.4 million to the underwriters, and we incurred expenses of $0.3 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 $100.2 million.

Loan and Security Agreement with Oxford

In October 2018, we entered into a loan and security agreement, or the Loan and Security Agreement, with Oxford Finance LLC, or Oxford. The Loan and Security Agreement provides for up to $65.0 million in term loans. Of the $65.0 million, we borrowed $30.0 million in October 2018. The remaining $35.0 million is available for draw ending on the earlier of March 31, 2019 or an event of default. Should we not draw all or a portion of the $35.0 million during the applicable draw timeframe, or if we prepay the entirety of the amount drawn during the applicable draw timeframe, we will be required to pay Oxford a non-utilization fee equal to 1.0% of the undrawn portion.

The Loan and Security Agreement provides for interest only payments through the payment date immediately prior to November 1, 2021, followed by 24 consecutive equal monthly payments of principal and interest in arrears starting on November 1, 2021 and continuing through the maturity date of October 1, 2023. All unpaid principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan and Security Agreement provides for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate reported in The Wall Street Journal on the last business day of the month that immediately precedes the month in which the interest will accrue plus 6.25%. The Loan and Security Agreement also provides for a final payment equal to 5.75% of the original principal amount of the term loans drawn, which final payment is due on October 1, 2023 or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

We have the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of (i) 3% of the original principal amount of the aggregate term loans drawn for any prepayment prior to the first anniversary of the applicable funding date, (ii) 2% of the original principal amount of the aggregate term loans drawn for any prepayment between the first and second anniversaries of the applicable funding date or (iii) 1% of the original principal amount of the aggregate term loans drawn for any prepayment after the second anniversary of the applicable funding date but before October 1, 2023. We also have the option to prepay the term loans in part, once in a three-month period, of an amount of $2.0 million or greater, subject to the same prepayment fees and other specified limitations.

Our obligations under the Loan and Security Agreement are secured by substantially all of our assets, except that the collateral does not include our intellectual property. However, we have agreed not to encumber any of our intellectual property. The Loan and Security Agreement contains customary representations, warranties and covenants, including covenants that limit our ability, subject to specified exceptions, to convey, sell, lease, transfer, assign or otherwise dispose of assets; engage in any business other than the businesses currently engaged in; liquidate or dissolve; undergo specified change of control events; create, incur, assume or be liable for indebtedness; create, incur, allow or suffer any liens on property; pay dividends and make other restricted payments; make investments; or enter into any material transactions with affiliates. The Loan and Security Agreement also contains specified financial covenants related to minimum consolidated future revenues.

The Loan and Security Agreement also contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill our obligations under the Loan and Security Agreement, the occurrence of a material adverse change, specified defaults or our failure to keep our common stock listed on the Nasdaq Stock Market. In the event of default, Oxford would be entitled to exercise its remedies thereunder, including the right to

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accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Loan and Security Agreement.

Cash Flows

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

	Year Ended December 31,		
	2018	2017	2016
	(In thousands)		
Net cash used in operating activities	$ (100,811)	$ (54,663)	$ (34,603)
Net cash provided by (used in) investing activities	9,367	(55,692)	(61,903)
Net cash provided by financing activities	128,261	100,386	116,826
Net increase (decrease) in cash and cash equivalents	$ 36,817	$ (9,969)	$ 20,320

Operating Activities

During the year ended December 31, 2018, operating activities used $100.8 million of cash primarily resulting from our net loss of $132.7 million, partially offset by changes in our operating assets and liabilities of $9.4 million, and non-cash adjustments of $23.2 million. Net cash provided by changes in our operating assets and liabilities during the year ended December 31, 2018 consisted of a $13.8 million increase in accounts payable and accrued expenses, which was partially offset by a $4.4 million increase in accounts receivable. The increase in accounts payable and accrued expenses was primarily driven by expenses incurred, but not yet paid, as of December 31, 2018, as well as the timing of vendor invoicing and payments. Expenses incurred, but not yet paid, as of December 31, 2018 primarily included sales and marketing expenses related to the commercial launch of ESKATA in the United States in May 2018, amounts payable for copay assistance and commercial rebates related to sales of RHOFADE which we began selling in December 2018, as well as expenses related to our Phase 3 clinical trials for A-101 45% Topical Solution, and our Phase 2 clinical trials for ATI-501 and ATI-502. The increase in accounts receivable was the result of the commercial launch of ESKATA in May 2018, and sales of RHOFADE which we acquired in November 2018. Non-cash expenses of $23.2 million were primarily composed of stock-based compensation expense.

During the year ended December 31, 2017, operating activities used $54.7 million of cash primarily resulting from our net loss of $68.5 million, partially offset by changes in our operating assets and liabilities of $0.9 million and non-cash adjustments of $13.0 million. Net cash used by changes in our operating assets and liabilities during the year ended December 31, 2017 consisted of a $4.3 million increase in prepaid expenses and other current assets offset by a $5.2

million increase in accounts payable and accrued expenses. The increase in prepaid expenses and other current assets was primarily due to a $2.0 million PDUFA fee paid to the FDA in conjunction with the filing of the NDA for ESKATA, as well as deposits made for clinical supplies and development activities that were incurred during 2018. The increase in accounts payable and accrued expenses was primarily due to an increase of $1.2 million in accrued bonuses payable due to increased headcount, $0.6 million payable to NST Consulting LLC in connection with the early termination of our sublease with them, as well as expenses incurred, but not yet paid, in connection with our Phase 2 clinical trials for A-101 45% Topical Solution, ATI-501 and ATI-502. Non-cash expenses of $13.0 million included stock-based compensation expense of $14.4 million, and $0.4 million of depreciation and amortization, partially offset by an adjustment to our deferred tax liability, net of $1.8 million which was the result of the Tax Cuts and Jobs Act of 2017 enacted on December 22, 2017.

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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 stock-based compensation expense, and $2.8 million resulting from the Vixen acquisition.

Investing Activities

During the year ended December 31, 2018, investing activities provided $9.4 million of cash, consisting of proceeds from sales and maturities of marketable securities of $239.4 million, partially offset by purchases of marketable securities of $161.6 million, $67.1 million for the purchase of RHOFADE, and purchases of equipment of $1.4 million.

During the year ended December 31, 2017, investing activities used $55.7 million of cash, consisting of purchases of marketable securities of $197.3 million, $9.6 million for the acquisition of Confluence and purchases of property and equipment of $1.2 million, partially offset by proceeds from sales and maturities of marketable securities of $152.5 million.

During the year ended December 31, 2016, investing activities used $61.9 million of cash, 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.

Financing Activities

During the year ended December 31, 2018, financing activities provided $128.3 million of cash and included net proceeds of $100.2 million received from our public offering of common stock in October 2018, $29.9 million of net borrowings pursuant to the Loan and Security Agreement with Oxford, and $0.6 million of cash received from the

exercise of employee stock options, partially offset by $1.8 million paid to the former Confluence equity holders as a result of the achievement of a development milestone and $0.6 million of capital lease payments.

During the year ended December 31, 2017, financing activities provided $100.4 million of cash and included $19.3 million of net proceeds received from the sale of common stock under our sales agreement with Cowen in April 2017, $80.9 million of net proceeds received from our public offering of common stock in August 2017, and $0.2 million of cash received from the exercise of employee stock options, partially offset by $0.1 million of capital lease payments for laboratory equipment.

During the year ended December 31, 2016, financing activities provided $116.8 million of cash and included $18.5 million of net proceeds received from the private placement of our common stock in June 2016, net proceeds of $98.2 million received from our public offering of common stock in November 2016, as well as $0.1 million of cash received from the exercise of employee stock options.

Funding Requirements

We plan to focus in the near term on the commercialization of ESKATA for the treatment of raised SKs, and RHOFADE for the treatment of persistent facial erythema associated with rosacea in adults, as well as the clinical development of our drug candidates. We anticipate we will incur net losses for the next several years as we continue to commercialize ESKATA and RHOFADE, continue the clinical development of A-101 45% Topical Solution for the treatment of common warts and continue research and development of ATI-501 and ATI-502 for the treatment of AA and other dermatological conditions, as well as the identification, research and development of other compounds. We plan to continue to invest in discovery efforts to explore additional drug candidates, build commercial capabilities and expand our

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corporate infrastructure. We may not be able to complete the development and initiate commercialization of these programs if, among other things, our clinical trials are not successful or if the FDA does not approve our drug candidates 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, sales, marketing and advertising costs, legal and other regulatory expenses, and administrative and overhead costs. In addition, in 2019 we plan to invest in a new research facility for our drug discovery operations. Our future funding requirements will be heavily determined by the resources needed to support the commercialization of ESKATA and RHOFADE, as well as the 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 LLC, 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 that appear in Item 8 of this Annual Report on Form 10-K based on our current operating assumptions including the commercialization of ESKATA and RHOFADE, conducting Phase 3 clinical trials for A-101 45% Topical Solution for the treatment of common warts, the continued development of ATI-501 and ATI-502 as potential treatments for AA and other dermatological indications, and the development of ATI-450 as a potential treatment for psoriasis and other dermatological conditions. 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 45% Topical Solution for the treatment of common warts, if approved, to complete the clinical development of ATI-501 and ATI-502, to develop our preclinical compounds, to support our discovery efforts, and to pursue in-licenses or acquisitions of other drug candidates. We also expect to incur significant expenses related to the commercialization of ESKATA and RHOFADE, including product manufacturing, sales, marketing, advertising and distribution costs. 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.

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.

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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 extent to which we in-license or acquire additional drug candidates and technologies;
- the number and development requirements of the drug candidates that we may pursue;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting pre-clinical and clinical trials for our drug candidates;
- the cost of commercializing ESKATA and RHOFADE and 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 received from commercial sales of ESKATA and RHOFADE and any of our drug candidates for which we receive marketing approval;
- the progress of obtaining marketing approval for ESKATA in select countries in the European Union and Norway;
- our ability to establish collaborations to commercialize ESKATA and RHOFADE outside the United States;
- 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; and
- the timing, receipt and amount of sales of, or milestone payments related to or royalties on, our current or future products or drug candidates, if any, as a result of licenses to, or partnership or collaborations with, third parties.

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, 2018 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	$ 3,000	$ 652	$ 1,816	$ 532	$ —
Capital lease commitments	1,775	591	1,184	—	—
Long-term debt commitments	30,000	—	2,500	27,500	—
Vixen annual commitment	400	100	300	—	—
Total	$ 35,175	$ 1,343	$ 5,800	$ 28,032	$ —

We occupy space for our headquarters in Wayne, Pennsylvania under a sublease agreement which has a term through October 2023. We lease office space in Malvern, Pennsylvania under an operating lease agreement which has a term through November 2019. We occupy office and laboratory space in St. Louis, Missouri under an operating lease agreement which has a term through May 2019.

We lease laboratory equipment used in our laboratory space in St. Louis, Missouri under two capital lease financing arrangements which have terms through October 2020 and December 2020.

We lease a fleet of automobiles for our sales force and other field-based employees under the terms of a master lease agreement. The lease term for each automobile begins on the date we take delivery and continues for a period of four years.

In October 2018, we borrowed $30.0 million under the Loan and Security Agreement with Oxford. We have the ability to borrow up to an additional $35.0 million ending on the earlier of March 31, 2019 or an event of default. Any amounts borrowed under the Loan and Security Agreement will be subject to interest only through October 2021, after which we will be required to make principal and interest payments through the maturity date of October 2023.

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Under various agreements, we may 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 ESKATA or other 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 also agreed to make a remaining payment of $3.0 million upon the achievement of a specified commercial milestone. In addition, we have agreed to pay royalties on sales of ESKATA or other related products at a low single-digit percentage of net sales, as defined in the agreement.

Under the Rigel License Agreement, 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 Rigel License 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 the Vixen Agreement, 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 an annual payment of $0.1 million through March 2022, which amounts are creditable against any specified future payments that may be paid under the Vixen Agreement. With respect to any products we commercialize under the Vixen 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 Vixen Agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

Under the Columbia License Agreement, 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 Columbia License Agreement, we will be obligated to pay Columbia a portion of any consideration Vixen receives from such sublicenses in specified circumstances.

Under the Confluence Agreement with the former Confluence equity holders, we are obligated to make remaining aggregate payments of up to $75.0 million upon the achievement of specified regulatory and commercialization milestones. With respect to any covered products we commercialize, we are obligated to pay a 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 Confluence Agreement, we will be obligated to pay a portion of any consideration we receive from such sublicenses in specified circumstances.

Under the Asset Purchase Agreement with Allergan pursuant to which we acquired intellectual property, we have agreed to pay Allergan royalties on net sales of RHOFADE ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related to a particular product, such as RHOFADE, have expired or, if later, November 30, 2028. In addition, we have agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. We have also agreed to pay Allergan a one-time payment of $5.0 million upon the achievement of a specified development milestone related to the potential development of an additional dermatology product.

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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.

Recently Issued and Adopted Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. We are evaluating the impact of ASU 2018-18 on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in Accounting Standards Codification, or ASC, 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. We are evaluating the impact of ASU 2018-15 on our consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. This update eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some of the existing disclosure requirements. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. We are evaluating the impact

of ASU 2018-13 on our consolidated financial statements.

In June 2018, the FASB, issued ASU 2018-07, Compensation—Stock Compensation (Topic 718). The amendments in this ASU expand the scope of Topic 718 to include stock-based compensation arrangements with non-employees except for specific guidance on option pricing model inputs and cost attribution. ASU 2018-07 is effective for annual reporting periods beginning after December 31, 2018, including interim periods within that year, and early adoption is permitted. We adopted this standard as of January 1, 2019, the impact of which on our consolidated financial statements was not significant.

In January 2017, the FASB issued 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 was permitted. We adopted this standard as of January 1, 2018, the impact of which on our consolidated financial statements was not significant.

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

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for annual reporting periods beginning after December 15, 2019, including interim periods within those years, and early adoption is permitted. We are assessing the potential impact of ASU 2016-13 on our consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, and ASU 2018-11, Targeted Improvements, both of which included a number of technical corrections and improvements, including additional options for transition. 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. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those annual periods, with early adoption permitted. The amendments in ASU 2016-02 must be applied to all leases existing at the date a company initially applies the standard. A company may choose to use either the effective date of ASU 2016-02, or the beginning of the earliest comparative period presented in the financial statements, as its date of initial application. We adopted the new standard on January 1, 2019 and used the effective date as the date of initial application. Our financial statements will not be updated, and the disclosures under the new standard will not be provided, for periods before January 1, 2019.

ASU 2016-02 provides optional practical expedients companies can elect to use in transition. We expect to elect practical expedients which allow us not to reassess prior conclusions about lease identification, lease classification and initial direct costs made under previous accounting standards. We are continuing to evaluate the effect of adoption of ASU 2016-02, and we estimate that both assets and liabilities will increase by $2.0 million to $2.5 million upon adoption, before considering deferred taxes. We do not expect the adoption of ASU 2016-02 to have a material impact on our consolidated statement of operations or cash flows.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Under this ASU, entities should recognize revenue in an amount that reflects the consideration to which they expect to be entitled to in exchange for goods and services provided. ASU 2014-09 was effective for annual reporting periods beginning after December 15, 2017. We adopted the provisions of this standard on January 1, 2018, using the modified retrospective transition method. We did not recognize any transition adjustments as a result of adopting ASU 2014-09 and, accordingly, comparative information has not been restated for the periods reported.

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.

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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.

The Loan and Security Agreement with Oxford provides for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate plus 6.25%. To the extent that any present or future credit facilities that we enter into are based on a floating interest rate, we will be subject to risks relating to changes in market interest rates. In periods of rising interest rates when we have such debt outstanding, our interest expense would increase. Based upon our debt outstanding under the Loan and Security Agreement of $30.0 million as of December 31, 2018, a 100 basis-point increase in the interest rate on our loan with Oxford would result in approximately $304,000 of additional interest expense on an annualized basis.

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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.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aclaris Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, of stockholders' equity and of cash flows for each of the three years in the period ended December 31, 2018, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2018 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania

March 18, 2019

We have served as the Company’s auditor since 2015.

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ACLARIS THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

(In thousands, except share and per share data)

	December 31, 2018	2017
Assets		
Current assets:		
Cash and cash equivalents	$ 57,019	$ 20,202
Marketable securities	110,953	173,655
Accounts receivable, net	4,861	481
Inventory	791	—
Prepaid expenses and other current assets	5,875	5,883
Total current assets	179,499	200,221
Marketable securities	—	14,997
Property and equipment, net	4,280	2,159
Intangible assets	72,951	7,349
Goodwill	18,504	18,504
Other assets	332	279
Total assets	$ 275,566	$ 243,509
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 14,755	$ 7,822
Accrued expenses	12,587	4,940
Total current liabilities	27,342	12,762
Other liabilities	1,703	558
Long-term debt	29,914	—
Contingent consideration	934	4,378
Deferred tax liability	549	549
Total liabilities	60,442	18,247
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at December 31, 2018 and December 31, 2017	—	—
Common stock, $0.00001 par value; 100,000,000 shares authorized at December 31, 2018 and December 31, 2017; 41,210,725 and 30,856,505 shares issued and outstanding at December 31, 2018 and December 31, 2017, respectively	—	—
Additional paid in capital	507,366	384,943
Accumulated other comprehensive loss	(69)	(246)
Accumulated deficit	(292,173)	(159,435)
Total stockholders' equity	215,124	225,262
Total liabilities and stockholders' equity	$ 275,566	$ 243,509

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, 2018	2017	2016
Revenues:			
Product sales, net	$ 3,940	$ —	$ —
Contract research	4,651	1,683	—
Other revenue	1,500	—	—
Total revenue, net	10,091	1,683	—
Cost of revenue	6,850	1,207	—
Gross profit	3,241	476	—
Operating expenses:			
Research and development	63,009	39,790	33,476
Sales and marketing	47,997	13,769	3,295
General and administrative	27,649	19,340	11,796
Total operating expenses	138,655	72,899	48,567
Loss from operations	(135,414)	(72,423)	(48,567)
Other income, net	2,676	2,070	488
Loss before income taxes	(132,738)	(70,353)	(48,079)
Provision for (benefit from) income taxes	—	(1,830)	—
Net loss	$ (132,738)	$ (68,523)	$ (48,079)
Net loss per share, basic and diluted	$ (4.03)	$ (2.44)	$ (2.25)
Weighted average common shares outstanding, basic and diluted	32,909,762	28,102,386	21,415,733
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities, net of tax of $0	$ 145	$ (121)	$ 105
Foreign currency translation adjustments	32	144	(225)
Total other comprehensive income (loss)	177	23	(120)
Comprehensive loss	$ (132,561)	$ (68,500)	$ (48,199)

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

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ACLARIS THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY

(In thousands, except share data)

	Common Stock		Additional Paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
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
Foreign currency translation adjustment	—	—	—	(225)	—	(225)
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
Issuance of common stock under the at-the-market sales agreement, net of offering costs of $691	635,000	—	19,311	—	—	19,311
Issuance of common stock in connection with public offering, net of offering costs of $5,352	3,747,602	—	80,918	—	—	80,918
Issuance of common stock in connection with the acquisition of Confluence	349,527		9,675	—	—	9,675
Exercise of stock options and vesting of RSUs	65,195	—	(62)	—	—	(62)

Unrealized loss on marketable securities	—	—	—	(121)	—	(121)
Foreign currency translation adjustment	—	—	—	144	—	144
Stock-based compensation expense	—	—	14,430	—	—	14,430
Net loss	—	—	—	—	(68,523)	(68,523)
Balance at December 31, 2017	30,856,505	—	384,943	(246)	(159,435)	225,262
Issuance of common stock in connection with public offering, net of offering costs of $6,669	9,941,750	—	100,205	—	—	100,205
Issuance of common stock in connection with the Confluence development milestone	253,181	—	2,215	—	—	2,215
Exercise of stock options and vesting of RSUs	159,289	—	(52)	—	—	(52)
Unrealized gain on marketable securities	—	—	—	145	—	145
Foreign currency translation adjustment	—	—	—	32	—	32
Stock-based compensation expense	—	—	20,055	—	—	20,055
Net loss	—	—	—	—	(132,738)	(132,738)
Balance at December 31, 2018	41,210,725	$ —	$ 507,366	$ (69)	$ (292,173)	$ 215,124

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, 2018	2017	2016
Cash flows from operating activities:			
Net loss	$ (132,738)	$ (68,523)	$ (48,079)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,879	402	120
Stock-based compensation expense	20,055	14,430	6,104
Change in fair value of contingent consideration	1,272	—	—
Payment of Confluence development milestone	(717)	—	—
Deferred taxes	—	(1,837)	—
Write-down of equipment held for sale	—	—	216
Non-cash charge related to Vixen acquisition	—	—	2,784
Changes in operating assets and liabilities:			
Accounts receivable	(4,380)	—	—
Inventory	102	—	—
Prepaid expenses and other assets	(40)	(4,306)	(8)
Accounts payable	6,964	4,564	1,810
Accrued expenses	6,792	607	2,450
Net cash used in operating activities	(100,811)	(54,663)	(34,603)
Cash flows from investing activities:			
Purchases of property and equipment	(1,356)	(1,235)	(232)
Acquisition of RHOFADE	(67,122)	—	—
Acquisition of Confluence, net of cash acquired	—	(9,647)	—
Purchases of marketable securities	(161,598)	(197,337)	(148,764)
Proceeds from sales and maturities of marketable securities	239,443	152,527	87,093
Net cash provided by (used in) investing activities	9,367	(55,692)	(61,903)
Cash flows from financing activities:			
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	19,311	—
Proceeds from issuance of common stock in connection with public offering, net of issuance costs	100,205	80,918	98,158
Proceeds from issuance of common stock in connection with private placement, net of issuance costs	—	—	18,547
Proceeds from debt financing, net of issuance costs	29,910	—	—
Capital lease payments	(648)	(78)	—
Proceeds from the exercise of employee stock options	577	235	121

Payment of Confluence development milestone	(1,783)	—	—
Net cash provided by financing activities	128,261	100,386	116,826
Net increase (decrease) in cash and cash equivalents	36,817	(9,969)	20,320
Cash and cash equivalents at beginning of period	20,202	30,171	9,851
Cash and cash equivalents at end of period	$ 57,019	$ 20,202	$ 30,171
Supplemental disclosure of non-cash investing and financing activities:			
Additions to property and equipment included in accounts payable	$ 161	$ 274	$ 11
Fair value of stock issued in connection with Confluence acquisition	$ —	$ 9,675	$ —
Fair value of stock issued in settlement of Confluence development milestone	$ 2,215	$ —	$ —
Property and equipment obtained pursuant to capital lease financing arrangements	$ 2,131	$ —	$ 2,355
Offering costs included in accounts payable	$ 210	$ 20	$ 250

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

Overview

Aclaris Therapeutics, Inc. was incorporated under the laws of the State of Delaware in 2012. In July 2015, Aclaris Therapeutics International Limited ("ATIL") was established under the laws of the United Kingdom as a wholly-owned subsidiary of Aclaris Therapeutics, Inc. In March 2016, Vixen Pharmaceuticals, Inc. ("Vixen") became a wholly-owned subsidiary of Aclaris Therapeutics, Inc., and in September 2018, Vixen was dissolved. In August 2017, Confluence Life Sciences, Inc., now known as Aclaris Life Sciences, Inc. ("Confluence") was acquired by Aclaris Therapeutics, Inc. and became a wholly-owned subsidiary thereof (see Note 3). Aclaris Therapeutics, Inc., ATIL, Vixen and Confluence are referred to collectively as the "Company". The Company is a physician-led biopharmaceutical company focused on dermatological and immuno-inflammatory diseases. The Company has two commercial products and a diverse pipeline of drug candidates. The Company's first commercial product, ESKATA (hydrogen peroxide) Topical Solution, 40% (w/w) ("ESKATA"), is a proprietary high concentration formulation of hydrogen peroxide that the Company is commercializing as an office-based prescription treatment for raised seborrheic keratosis ("SK"), a common non malignant skin tumor. The Company submitted a New Drug Application ("NDA") for ESKATA to the U.S. Food and Drug Administration ("FDA") in February 2017, and it was approved in December 2017. The Company launched ESKATA in the United States in May 2018. In November 2018, the Company acquired the worldwide rights to a second commercial product, RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE") (see Note 3).

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, 2018, the Company had cash, cash equivalents and marketable securities of $167,972 and an accumulated deficit of $292,173. Since inception, the Company has incurred net losses and negative cash flows from its operations. Prior to the acquisition of Confluence in August 2017, the Company had never generated any revenue. There can be 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 preclinical testing of the Company's drug candidates, and commercialization of

ESKATA and RHOFADE will require significant additional financing. 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 ("GAAP"). The consolidated financial statements of the Company include the accounts of the operating parent company, Aclaris Therapeutics, Inc., and its wholly-owned subsidiaries, Confluence, ATIL and Vixen. All significant 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, contingent consideration 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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Revenue Recognition

The Company accounts for revenue in accordance with Accounting Standards Codification ("ASC") Topic 606, Revenue from Contracts with Customers. Under ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services.

To determine revenue recognition in accordance with ASC Topic 606, the Company performs the following five steps: (i) identify the contract(s) with a customer, (ii) identify the performance obligations in the contract, (iii) determine the transaction price, (iv) allocate the transaction price to the performance obligations in the contract, and (v) recognize revenue when (or as) performance obligations are satisfied. At contract inception, the Company assesses the goods or services promised within a contract with a customer to identify the performance obligations, and to determine if they are distinct. The Company recognizes the revenue that is allocated to each distinct performance obligation when (or as) that performance obligation is satisfied. The Company only recognizes revenue when collection of the consideration it is entitled to under a contract with a customer is probable. The Company expenses incremental costs of contracts with direct and indirect customers, which generally include sales commissions, in the period they are incurred.

Product Sales, net

The Company sells ESKATA and RHOFADE to a limited number of wholesalers in the United States (collectively, its "Customers"). These Customers subsequently resell the Company's products to pharmacies and health care providers. In addition to distribution agreements with Customers, the Company may enter into arrangements with health care providers, third-party payors, pharmacy benefit managers, and group purchasing organizations ("GPOs") which provide for government mandated and/or privately negotiated rebates, chargebacks, and discounts, with respect to the purchase of the Company's products.

The Company recognizes revenue from product sales at the point the Customer obtains control of the product, which generally occurs upon delivery, and includes estimates of variable consideration in the same period revenue is recognized. Components of variable consideration include trade discounts and allowances, product returns, government rebates, discounts and rebates, other incentives such as patient co-pay assistance, and other fee for service amounts. Variable consideration is recorded on the consolidated balance sheet as either a reduction of accounts receivable, if payable to a customer, or as a current liability, if payable to a third-party other than a customer. The Company considers all relevant information when estimating variable consideration such as current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of net revenue the Company can recognize is constrained by estimates of variable consideration which are included in the transaction price. Payment terms with Customers do not exceed one year and,

therefore, the Company does not account for a financing component in its arrangements. The Company expenses incremental costs of obtaining a contract with a Customer, including sales commissions, when incurred as the period of benefit is less than one year. Shipping and handling costs for product shipments to Customers are recorded as sales and marketing expenses in the consolidated statement of operations.

Trade Discounts and Allowances - The Company may provide Customers with trade discounts, rebates, allowances or other incentives. The Company records an estimate for these items as a reduction of revenue in the same period the revenue is recognized.

Government and Payor Rebates - The Company may contract with certain third-party payors, primarily health insurance companies, pharmacy benefit managers and government programs, for the payment of rebates with respect to utilization of its products. The Company also has agreements with GPOs that provide for administrative fees and discounted pricing in the form of volume-based rebates. The Company is also subject to discount obligations under state Medicaid programs and Medicare. The Company records an estimate for these rebates as a reduction of revenue in the same period the revenue is recognized.

Other Incentives - Other incentives includes the Company’s co-pay assistance program which is intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by

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payors. The Company estimates and records an accrual for these incentives as a reduction of revenue in the period the revenue is recognized. The Company estimates amounts for co-pay assistance based upon the number of claims and the cost per claim that the Company expects to receive associated with product that has been sold to Customers but remains in the distribution channel at the end of each reporting period.

Product Returns - Consistent with industry practice, the Company has a product returns policy that provides Customers a right of return for product purchased within a specified period prior to and subsequent to the product's expiration date. The right of return lapses upon shipment of the goods to a patient. The Company records an estimate for the amount of its products which may be returned as a reduction of revenue in the period the related revenue is recognized. The Company's estimates for product returns are based upon available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. There is no returns liability associated with sales of ESKATA as the Company has a no returns policy for this product.

Product sales, net included the following for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31,		
	2018	2017	2016
ESKATA	$ 2,804	$ —	$ —
RHOFADE	1,136	—	—
Total product revenue, net	$ 3,940	$ —	$ —

Contract Research

The Company earns contract research revenue from the provision of laboratory services to clients through Confluence, its wholly-owned subsidiary. Contract research revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis and are generally billed on a monthly basis in arrears for services rendered. Revenue related to these contracts is generally recognized as the laboratory services are performed, based upon the rates specified in the contracts. Under ASC Topic 606, the Company elected to apply the "right to invoice" practical expedient when recognizing contract research revenue. The Company recognizes contract research revenue in the amount to which it has the right to invoice.

The Company has also received revenue from grants under the Small Business Innovation Research program of the National Institutes of Health ("NIH"). During the year ended December 31, 2018, the Company had two active grants from NIH which were related to early-stage research. As of December 31, 2018, there were no remaining funds

available to the Company under the grants. The Company recognizes revenue related to grants as amounts become reimbursable under each grant, which is generally when research is performed, and the related costs are incurred.

Other Revenue

Licenses of Intellectual Property – The Company recognizes revenue received from non-refundable, upfront fees related to the licensing of intellectual property when the intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the license has been transferred to the customer, and the customer is able to use and benefit from the license.

Milestone Payments - At the inception of each arrangement that includes milestone payments, the Company evaluates whether the milestones are considered probable of being reached and estimates the amount to be included in the transaction price using the most likely amount method. If it is probable that a significant revenue reversal would not occur, the associated milestone value is included in the amount allocated to the license of intellectual property. Milestone payments that are not within the control of the Company or the customer, such as regulatory approvals, are not considered probable of being achieved until those approvals are received.

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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. 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.

Other Assets

In February 2017, the Company paid a $2,000 PDUFA fee to the FDA in conjunction with the filing of its NDA for ESKATA. The Company requested a waiver and refund of this PDUFA fee, which was approved by the FDA in December 2017, and was refunded to the Company in January 2018.

Inventory

Inventory includes the third-party cost of manufacturing and assembly of finished product, quality control and other overhead costs. Inventory is stated at the lower of cost or net realizable value. Inventory is adjusted for short-dated, unmarketable inventory equal to the difference between the cost of inventory and the estimated value based upon

assumptions about future demand and market conditions. The Company had $791 and $0 of inventory as of December 31, 2018 and 2017, respectively, which was comprised primarily of finished goods.

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, in other assets on its consolidated balance sheet. 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 were $0 and $62 as of December 31, 2018 and 2017, 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 and laboratory 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.

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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. The Company recorded an impairment charge of $216 in the year ended December 31, 2016 for equipment that was previously classified as held for sale. The impairment charge was included in research and development expense on the Company's consolidated statement of operations. The Company had no assets classified as held for sale as of December 31, 2018 and 2017.

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.

Intangible Assets

Intangible assets include both finite-lived and indefinite-lived assets. Finite-lived intangible assets are amortized over their estimated useful life based on the pattern over which the intangible assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the straight-line method of amortization is used. Finite-lived intangible assets consist of a research technology platform the Company acquired through the acquisition of Confluence and the intellectual property rights related to RHOFADE. Indefinite-lived intangible assets consist of an in-process research and development ("IPR&D") drug candidate acquired through the acquisition of Confluence. IPR&D assets are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. The cost of IPR&D assets is either amortized over their estimated useful life beginning when the underlying drug candidate is approved and launched commercially, or expensed immediately if development of the drug candidate is abandoned.

Finite-lived intangible assets are tested for impairment when events or changes in circumstances indicate that the carrying value of the asset may not be recoverable. Indefinite-lived intangible assets are tested for impairment at least annually, which the Company performs during the fourth quarter, or when indicators of an impairment are present. The Company recognizes impairment losses when and to the extent that the estimated fair value of an indefinite-lived intangible asset is less than its carrying value.

Goodwill

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which the Company performs during the fourth quarter, or when indicators of an impairment are present. The Company considers each of its operating segments, dermatology therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. The Company has attributed the full amount of the goodwill acquired with Confluence, or $18,504, to the dermatology therapeutics segment. The annual impairment test performed by the Company is a qualitative assessment based upon current facts and circumstances related to operations of the dermatology therapeutics segment. If the qualitative assessment indicates an impairment may be present, the Company would perform the required quantitative analysis and an impairment charge would be recognized to the extent that the estimated fair value of the reporting unit is less than its carrying amount. However, any loss recognized would not exceed the total amount of goodwill allocated to that reporting unit. The Company concluded goodwill was not impaired as of December 31, 2018 and 2017.

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Contingent Consideration

The Company initially recorded the contingent consideration related to future potential payments based upon the achievement of certain development, regulatory and commercial milestones, resulting from the acquisition of Confluence, at its estimated fair value on the date of acquisition. Changes in fair value reflect new information about the likelihood of the payment of the contingent consideration and the passage of time. Future changes in the fair value of the contingent consideration, if any, will be recorded as income or expense in the Company's consolidated statement of operations.

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.

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.

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 Company's initial public offering in October 2015 ("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

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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.

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 statement of operations. The Company has not utilized foreign currency hedging strategies to mitigate the effect of its foreign currency exposure.

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.

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.

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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. Since the Company was in a net loss position basic and diluted net loss per share was the same for each of the periods presented.

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 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, marketable securities and contingent consideration 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. The carrying value of the Company’s debt approximates fair value because interest is a floating rate based on the 30-day U.S. LIBOR rate, and is therefore reflective of market rates.

Concentration of Credit Risk and of Significant Customers and 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's top five customers represented 83% of aggregate gross revenue from product sales and contract research revenue for the year ended December 31, 2018. The Company's top five customers represented 70% of total contract research revenue earned from August 3, 2017, the date of acquisition of Confluence, through December 31, 2017. The Company did not have product sales during the year ended December 31, 2017.

The Company is dependent on third party manufacturers to supply products for commercial distribution, as well as for research and development activities, including preclinical and clinical testing. These activities could be adversely affected by a significant interruption in the supply of active pharmaceutical ingredients and other components.

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Segment Reporting

Operating segments are components of a company for which separate financial information is available and evaluated regularly by the chief operating decision maker in assessing performance and deciding how to allocate resources. The Company reports two segments, dermatology therapeutics and contract research, which are primarily based on its operating segments and operating results used to assess performance. The dermatology therapeutics segment is focused on dermatological and immuno-inflammatory diseases. The contract research segment is focused on providing laboratory services to pharmaceutical and biotech companies looking to supplement their research and development efforts with difficult-to-execute specialty skills and programs. The Company does not allocate assets by segment.

Recently Issued and Adopted Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The amendments in this ASU are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2019, with early adoption permitted. The Company is evaluating the impact of ASU 2018-18 on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-15, Intangibles—Goodwill and Other—Internal-Use Software (Subtopic 350-40). ASU 2018-15 requires a customer in a cloud computing arrangement that is a service contract to follow the internal-use software guidance in ASC 350-40 to determine which implementation costs to capitalize as assets or expense as incurred. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. The Company is evaluating the impact of ASU 2018-15 on its consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, Fair Value Measurement (Topic 820). The FASB developed the amendments to ASC 820 as part of its broader disclosure framework project, which aims to improve the effectiveness of disclosures in the notes to financial statements by focusing on requirements that clearly communicate the most important information to users of the financial statements. This update eliminates certain disclosure requirements for fair value measurements for all entities, requires public entities to disclose certain new information and modifies some of the existing disclosure requirements. The standard will be effective for fiscal years beginning after December 15, 2019, including interim periods within such fiscal years, with early adoption permitted. The Company is evaluating the impact of ASU 2018-13 on its consolidated financial statements.

In June 2018, the FASB issued ASU 2018-07, Compensation—Stock Compensation (Topic 718). The amendments in this ASU expand the scope of Topic 718 to include stock-based compensation arrangements with nonemployees except for specific guidance on option pricing model inputs and cost attribution. ASU 2018-07 is effective for annual reporting periods beginning after December 31, 2018, including interim periods within that year, and early adoption is permitted. The Company adopted the provisions of this standard on January 1, 2019, the impact of which on its consolidated financial statements was not significant.

In January 2017, the FASB issued 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 is permitted. The Company adopted the provisions of this standard on January 1, 2018, the impact of which on its consolidated financial statements was not significant.

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 is permitted. The Company is assessing the potential impact of ASU 2016-13 on its consolidated financial

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statements.

In February 2016, the FASB issued ASU 2016-02, Leases (Topic 842). In July 2018, the FASB issued ASU 2018-10, Codification Improvements to Topic 842, Leases, and 2018-11, Targeted Improvements, which included a number of technical corrections and improvements, including additional options for transition. 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. The amendments in ASU 2016-02 must be applied to all leases existing at the date a company initially applies the standard. A company may choose to use either the effective date of ASU 2016-02, or the beginning of the earliest comparative period presented in the financial statements, as its date of initial application. The Company adopted the new standard on January 1, 2019 and used the effective date as its date of initial application. The Company's financial statements will not be updated, and the disclosures under the new standard will not be provided, for periods before January 1, 2019.

ASU 2016-02 provides optional practical expedients companies can elect to use in transition. The Company expects to elect practical expedients which allow it not to reassess prior conclusions about lease identification, lease classification and initial direct costs made under previous accounting standards. The Company continues to evaluate the effect of adoption of ASU 2016-02, and estimates both assets and liabilities will increase by $2,000 to $2,500 upon adoption, before considering deferred taxes. The Company does not expect the adoption of ASU 2016-02 will have a material impact on its consolidated statement of operations or cash flows.

In May 2014, the FASB issued ASU 2014-09, Revenue from Contracts with Customers (Topic 606). Under this ASU, entities should recognize revenue in an amount that reflects the consideration to which they expect to be entitled to in exchange for goods and services provided. ASU 2014-09 was effective for annual reporting periods beginning after December 15, 2017. The Company did not recognize any transition adjustments as a result of adopting ASU 2014-09 and, accordingly, comparative information has not been restated for the periods reported.

3. Acquisitions

RHOFADE

In November 2018, the Company completed the acquisition of RHOFADE from Allergan Sales, LLC ("Allergan") pursuant to the Asset Purchase Agreement dated as of October 15, 2018 (the "APA"). Pursuant to the APA, the

Company acquired the worldwide rights to RHOFADE, which includes an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property.

The following table summarizes the aggregate amount paid for the assets acquired by the Company in connection with the acquisition of RHOFADE:

Cash paid to Allergan at closing	$ 59,574
Cash deposited in escrow at closing	6,500
Transaction costs	1,048
Total purchase price of assets acquired	$ 67,122

The Company has also agreed to pay Allergan a one-time payment of $5,000 upon the achievement of a specified development milestone related to the potential development of an additional dermatology product. In addition, the Company has agreed to pay Allergan specified royalties, ranging from a mid-single digit percentage to a mid-teen percentage of net sales, subject to specified reductions, limitations and other adjustments, on a country-by-country basis until the date that the patent rights related RHOFADE have expired or, if later, November 30, 2028. In addition, the Company has agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Members of the Company's management team, including Neal Walker, Frank Ruffo, Christopher Powala and Stuart Shanler, as well as Stephen Tullman, the chairman of the Company's board of directors, are former stockholders of Vicept Therapeutics, Inc., and Dr. Shanler is also a current member of Aspect Pharmaceuticals, LLC. In their capacities as current or former holders of equity interests in these

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entities, these individuals may be entitled to receive a portion of the potential future payments payable by the Company. The Company incurred an aggregate expense of $165 and $0 related to royalty payments under these agreements during the years ended December 31, 2018 and 2017, respectively.

The acquisition of RHOFADE has been accounted for as an asset acquisition in accordance with FASB ASC 805-50, rather than as a business combination. As an asset acquisition, the cost to acquire the group of assets is allocated to the individual assets acquired or liabilities assumed based on their relative fair values. The relative fair values of identifiable tangible and intangible assets assumed from the acquisition of RHOFADE are based on estimates of fair value using assumptions that the Company believes is reasonable. The Company accounted for the acquisition of RHOFADE as an asset acquisition because substantially all of the fair value of the assets acquired is concentrated in a single asset, the RHOFADE product rights. ASC 805-10-55-5A, which sets forth a screen test, provides that if substantially all of the fair value of the assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the assets acquired are not considered to be a business.

The following table summarizes the fair value of assets acquired in the acquisition of RHOFADE:

Inventory	$ 893
Intangible assets, net	66,229
Total assets acquired	$ 67,122

The fair value of finished goods inventory acquired was estimated using net selling price less the costs of disposal and a reasonable profit for the disposal efforts. Raw material was valued at current replacement cost, which approximated the seller’s carrying value. The intangible asset for the RHOFADE product rights will be amortized on a straight-line basis over a period of 10 years. The Company believes this pattern of amortization reflects the expected benefits to be realized from commercializing RHOFADE. In addition, the 10-year useful life is based upon expiration dates of key patents underlying the RHOFADE intellectual property.

Confluence

In August 2017, the Company acquired Confluence, at which time, Confluence became a wholly-owned subsidiary of the Company. The Company gave aggregate consideration with a fair value of $24,322 to the equity holders of Confluence. The following table summarizes the fair value of total consideration given to the Confluence equity holders in connection with the acquisition:

Cash consideration paid	$ 10,269
Aclaris common stock issued	9,675
Contingent consideration	4,378
Total fair value of consideration to Confluence equity holders	$ 24,322

The Company accounted for the acquisition of Confluence as a business combination using the acquisition method of accounting. Under the acquisition method of accounting, the assets acquired and liabilities assumed in this transaction were recorded at their respective fair values. The following table summarizes the fair value of assets acquired and liabilities assumed in the acquisition of Confluence:

Cash and cash equivalents	$ 622
Accounts receivable, net	574
Other current assets	89
Property and equipment	268
Other intangible assets	751
IPR&D	6,629
Goodwill	18,504
Total assets acquired	27,437
Accounts payable and accrued expenses	656
Deferred tax liability	2,386

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Other liabilities	73
Total liabilities assumed	3,115
Total net assets acquired	$ 24,322

The fair value of the IPR&D and the other intangible assets acquired was determined using a replacement cost method, which estimated the cost that would be required to rebuild the intangible assets identified in the acquisition of Confluence. The acquisition of Confluence resulted in the recognition of goodwill in the amount of $18,504 which represents the value of new products and technologies to be developed in the future as well as the value of the employee workforce acquired.

In November 2018, the Company achieved a development milestone specified in the merger agreement with Confluence equity holders. The milestone payment to the Confluence equity holders was comprised of $2,500 in cash and 253,208 shares of the Company's common stock with a fair value of $2,216. The Company also agreed to pay the Confluence equity holders aggregate additional milestone payments of up to $75,000, based upon the achievement of specified regulatory and commercial milestones. In addition, the Company has agreed to pay the Confluence equity holders royalty payments calculated as a 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. In addition, if the Company sells, licenses or transfers any of the intellectual property acquired from Confluence, the Company will be obligated to pay the Confluence equity holders a portion of any incremental consideration (in excess of the development and milestone payments described above) that the Company receives from such sales, licenses or transfers in specified circumstances.

The following supplemental unaudited pro forma information presents the Company's financial results, for the periods presented, as if the acquisition of Confluence had occurred on January 1, 2016. This supplemental unaudited pro forma financial information has been prepared for comparative purposes only, and is not necessarily indicative of what actual results would have been had the acquisition of Confluence occurred on January 1, 2016, nor is this information indicative of future results.

	Year Ended December 31,		
	2018	2017	2016
Revenue	$ 10,091	$ 4,365	$ 3,693
Gross profit	3,241	1,347	1,652
Total operating expenses	138,655	73,810	51,277
Net loss	(132,738)	(70,391)	(49,148)

The supplemental unaudited pro forma financial results for the year ended December 31, 2017 includes adjustments to exclude $1,351 of acquisition-related expenses, and $888 to exclude revenue billed to the Company by Confluence. The supplemental unaudited pro forma financial results for the year ended December 31, 2017 also includes an adjustment for amortization expense related to the other intangible asset acquired.

There were no acquisition-related expenses incurred, or revenue billed to the Company by Confluence for the year ended December 31, 2016, and accordingly, no adjustment is necessary for these items in the supplemental pro forma financial results for that year. The supplemental unaudited pro forma financial results for the year ended December 31, 2016 includes an adjustment for amortization expense related to the other intangible assets acquired.

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4. 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, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 49,766	$ 4,992	$ —	$ 54,758
Marketable securities	—	110,953	—	110,953
Total Assets	$ 49,766	$ 115,945	$ —	$ 165,711
Liabilities:				
Acquisition-related contingent consideration	$ —	$ —	$ 934	$ 934
Total liabilities	$ —	$ —	$ 934	$ 934

	December 31, 2017			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 19,339	$ —	$ —	$ 19,339
Marketable securities	—	188,652	—	188,652
Total Assets	$ 19,339	$ 188,652	$ —	$ 207,991
Liabilities:				
Acquisition-related contingent consideration	$ —	$ —	$ 4,378	$ 4,378
Total liabilities	$ —	$ —	$ 4,378	$ 4,378

As of December 31, 2018 and 2017, the Company's cash equivalents consisted of investments with maturities of less than three months and included a money market fund and commercial paper which were valued based upon Level 1 inputs, and commercial paper, government obligations 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. During the years ended December 31, 2018 and 2017, there were no transfers between Level 1, Level 2 and Level 3. The reduction in acquisition-related contingent consideration of $3,444 during the year ended December 31, 2018 was primarily due to the achievement of a specified development milestone in November 2018 which resulted in the Company paying cash of $2,500 and issuing common stock with a fair value of $2,216 to the former Confluence equity holders. This reduction was partially offset by an adjustment of $1,272 to increase the value of the liability related to the achievement of the specified development milestone.

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As of December 31, 2018 and 2017, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

	December 31, 2018			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 5,030	$ —	$ (14)	$ 5,016
Commercial paper	67,159	—	—	67,159
Asset-backed securities	21,745	—	(8)	21,737
U.S. government agency debt securities	17,044	—	(3)	17,041
Total marketable securities	$ 110,978	$ —	$ (25)	$ 110,953

	December 31, 2017			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 37,401	$ —	$ (68)	$ 37,333
Commercial paper	85,202	—	—	85,202
Asset-backed securities	16,708	—	(13)	16,695
U.S. government agency debt securities	49,511	—	(89)	49,422
Total marketable securities	$ 188,822	$ —	$ (170)	$ 188,652

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31,	
	2018	2017
Computer equipment	$ 1,292	$ 650
Fleet vehicles	2,131	—
Manufacturing equipment	604	511

Lab equipment	1,068	721
Furniture and fixtures	524	327
Leasehold improvements	332	430
Property and equipment, gross	5,951	2,639
Accumulated depreciation	(1,671)	(480)
Property and equipment, net	$ 4,280	$ 2,159

Depreciation expense was $1,248, $370 and $120 for the years ended December 31, 2018, 2017 and 2016, respectively.

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6. Intangible Assets

Intangible assets consisted of the following:

	Remaining Life	Gross Cost December 31, 2018	Gross Cost December 31, 2017	Accumulated Amortization December 31, 2018	Accumulated Amortization December 31, 2017
RHOFADE product rights	9.9	$ 66,229	$ —	$ 552	$ —
Other intangible assets	8.6	751	751	106	31
Total definite-lived intangible assets		66,980	751	658	31
IPR&D	na	6,629	6,629	—	—
Total intangible assets, net		$ 73,609	$ 7,380	$ 658	$ 31

Amortization expense was $627, $31 and $0 for the years ended December 31, 2018, 2017 and 2016, respectively

As of December 31, 2018, estimated future amortization expenses is as follows:

Year Ending December 31,	
2019	$ 6,698
2020	6,698
2021	6,698
2022	6,698
2023	6,698
Thereafter	32,832
Total	$ 66,322

7. Accrued Expenses

Accrued expenses consisted of the following:

	December 31,	
	2018	2017
Employee compensation expenses	$ 5,293	$ 3,010
Sales incentives and rebates	2,650	—
Marketing expenses	453	39
Research and development expenses	1,437	627
Capital leases, current portion	601	142
Professional fees	1,123	108
Payable to NST	—	590
Other	1,030	424
Total accrued expenses	$ 12,587	$ 4,940

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8. Debt

Loan and Security Agreement – Oxford Finance LLC

In October 2018, the Company entered into a Loan and Security Agreement ("Loan Agreement") with Oxford Finance LLC, a Delaware limited liability company ("Oxford"). The Loan Agreement provides for up to $65,000 in term loans (the "Term Loan Facility"). Of the $65,000, the Company borrowed $30,000 in October 2018. The remaining $35,000 is available to be borrowed until the earlier of March 31, 2019 or an event of default. Should the Company not draw all of the Term Loan Facility, or repay the entirety of the amount drawn during the applicable draw timeframe, the Company will be required to pay a non-utilization fee equal to 1.0% of the undrawn portion of the Term Loan Facility.

The Loan Agreement provides for interest only payments through November 2021, followed by 24 consecutive equal monthly payments of principal and interest in arrears starting on November 2021 and continuing through the maturity date of October 2023. All unpaid principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan Agreement provides for an annual interest rate equal to the greater of (i) 8.35% and (ii) the 30-day U.S. LIBOR rate plus 6.25%. The Loan Agreement also provides for a final payment fee equal to 5.75% of the original principal amount of the term loans drawn under the Term Loan Facility, which final payment is due on October 1, 2023 or upon the prepayment of the facility or the acceleration of amounts due under the facility as a result of an event of default.

The Company has the option to prepay the outstanding balance of the term loans in full, subject to a prepayment fee of (i) 3% of the original principal amount of the aggregate term loans drawn for any prepayment prior to the first anniversary of the date such term loan was funded, (ii) 2% of the original principal amount of the aggregate term loans drawn for any prepayment between the first and second anniversaries of the date such term loan was funded or (iii) 1% of the original principal amount of the aggregate term loans drawn for any prepayment after the second anniversary of the funding date but before October 1, 2023. The Company also has the option to prepay the term loans in part, once in a three-month period, of an amount of $2,000 or greater, subject to the same prepayment fees and other specified limitations.

The Term Loan Facility is secured by substantially all of the Company's assets, except that the collateral does not include the Company's intellectual property, and the Company has agreed not to encumber any of its intellectual property. The Loan Agreement contains customary representations, warranties and covenants by the Company. The Loan Agreement also contains specified financial covenants related to minimum consolidated future revenues of the Company.

9. Stockholders' Equity

Preferred Stock

As of December 31, 2018 and 2017, 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, 2018 and 2017.

Common Stock

As of December 31, 2018 and 2017, the Company's amended and restated certificate of incorporation 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 have been declared through December 31, 2018.

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Private Placement

In June 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.

November 2016 Public Offering

In November 2016, the Company's registration statement on Form S-3 was declared effective by the Securities and Exchange Commission. On November 23, 2016, the Company closed a follow-on public offering in which 4,000,000 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 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 offering, including the underwriters' exercise of their option to purchase additional shares. In addition, the Company incurred expenses of $188 in connection with the offering. The net offering proceeds received by the Company, after deducting underwriting discounts, commissions and offering expenses, were $98,158.

At-The-Market Equity Offering

In November 2016, the Company entered into an at-the-market sales agreement with Cowen and Company, LLC ("Cowen") to sell the Company's securities under the Company's registration statement on Form S-3. In October 2018, the Company terminated the at-the-market sales agreement with Cowen. During the year ended December 31, 2018, the Company did not issue any shares of common stock under the at-the-market sales agreement. As of December 31, 2018, the Company had issued and sold an aggregate of 635,000 shares of common stock under the at-the-market sales agreement at a weighted average price per share of $31.50, for aggregate gross proceeds of $20,003. The Company incurred expenses of $691 in connection with the shares issued under the at-the-market sales agreement.

August 2017 Public Offering

In August 2017, the Company entered into an underwriting agreement pursuant to which the Company issued and sold 3,747,602 shares of common stock under the Company's registration statement on Form S-3, including the underwriters' partial exercise of their option to purchase additional shares. The shares of common stock were sold to the public at a price of $23.02 per share, for gross proceeds of $86,270.

The Company paid underwriting discounts and commissions of $5,176 to the underwriters in connection with the offering. In addition, the Company incurred expenses of $176 in connection with the offering. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and offering expenses, were $80,918.

October 2018 Public Offering

In October 2018, the Company entered into an underwriting agreement pursuant to which the Company issued and sold 9,941,750 shares of common stock under registration statements on Form S-3, including the underwriters' full exercise of their option to purchase additional shares. The shares of common stock were sold to the public at a price of $10.75 per share, for gross proceeds of $106,874. The Company paid underwriting discounts and commissions of $6,412 to the underwriters in connection with the offering. In addition, the Company incurred expenses of $257 in connection with the offering. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and offering expenses, were $100,205.

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10. Stock Based Awards

2017 Inducement Plan

In July 2017, the Company's board of directors adopted the 2017 Inducement Plan (the "2017 Inducement Plan"). The 2017 Inducement Plan is a non-shareholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The only employees eligible to receive grants of awards under the 2017 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq rules, generally including individuals who were not previously an employee or director of the Company. Under the terms of the 2017 Inducement Plan the Company may grant up to 1,000,000 shares of common stock pursuant to nonqualified stock options, stock appreciation rights, restricted stock awards, RSUs, and other stock awards. All shares of common stock that were eligible for issuance under the 2017 Inducement Plan after October 1, 2018, including any shares underlying any awards that expire or are otherwise terminated, reacquired to satisfy tax withholding obligations, settled in cash or repurchased by the Company in the future that would have been eligible for re-issuance under the 2017 Inducement Plan, were retired.

2015 Equity Incentive Plan

In September 2015, the Company's board of directors adopted the 2015 Equity Incentive Plan (the "2015 Plan"), and the Company's stockholders approved the 2015 Plan. The 2015 Plan became effective in connection with the Company's IPO. Beginning 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, nonqualified stock options, stock appreciation rights, restricted stock awards, RSU awards, performance stock awards, cash-based awards and other stock-based awards. The number of shares initially reserved for issuance under the 2015 Plan was 1,643,872 shares of common stock. The number of shares of common stock that may be issued under the 2015 Plan will automatically increase on January 1 of each year 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, 2018, 1,616,362 shares remained available for grant under the 2015 Plan. As of January 1, 2019, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 1,648,429 shares.

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 948,761 and 984,720 were outstanding as of December 31, 2018 and 2017, 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.

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, 2018, 2017 and 2016 were as follows:

	Year Ended December 31,		
	2018	2017	2016
Risk-free interest rate	2.66 %	1.93 %	2.06 %
Expected term (in years)	6.3	6.2	6.5
Expected volatility	96.78 %	94.19 %	94.86 %
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.

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Stock Options

The following table summarizes stock option activity for the years ended December 31, 2018, 2017 and 2016:

	Number of Shares		Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2015	1,738,524		$ 13.23	9.51	$ 24,722
Granted	1,083,919		27.12		
Exercised	(51,980)		—		
Forfeited and cancelled	(68,113)		—		
Outstanding as of December 31, 2016	2,702,350		$ 18.94	9.05	24,434
Granted	790,100		26.21		
Exercised	(36,738)		6.40		
Forfeited and cancelled	(126,955)		22.05		
Outstanding as of December 31, 2017	3,328,757		$ 20.69	8.28	$ 19,812
Granted	1,459,800		20.97		
Exercised	(59,450)		9.70		
Forfeited and cancelled	(447,026)		24.62		
Outstanding as of December 31, 2018	4,282,081		$ 20.53	7.91	$ 2,404
Options vested and expected to vest as of December 31, 2018	4,282,081		$ 20.53	7.91	$ 2,404
Options exercisable as of December 31, 2018	1,908,561	(1)	$ 17.53	7.02	$ 2,404

(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, 2018.

The weighted average grant date fair value of stock options granted during the years ended December 31, 2018, 2017 and 2016 was $16.55, $20.28 and $21.16 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, 2018, 2017 and 2016.

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
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
Granted	117,883	26.27
Vested	(40,705)	26.89
Forfeited and cancelled	(13,239)	27.53
Outstanding as of December 31, 2017	283,553	$ 27.02
Granted	552,060	19.03
Vested	(140,497)	27.22
Forfeited and cancelled	(68,709)	23.65
Outstanding as of December 31, 2018	626,407	$ 20.30

Stock Based Compensation

The following table summarizes stock-based compensation expense recorded by the Company for the years ended December 31, 2018, 2017 and 2016:

	Year Ended December 31, 2018	2017	2016
Cost of revenue	$ 766	$ 211	$ —
Research and development	6,480	5,471	2,291
Sales and marketing	3,492	1,851	—
General and administrative	9,317	6,897	3,813
Total stock-based compensation expense	$ 20,055	$ 14,430	$ 6,104

As of December 31, 2018, the Company had unrecognized stock based compensation expense for stock options and RSUs of $35,909 and $9,409, respectively, which is expected to be recognized over weighted average periods of 2.54 years and 2.90 years, respectively.

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11. Net Loss per Share

Basic and diluted net loss per share is summarized in the following table:

	Year Ended December 31, 2018	2017	2016
Numerator:			
Net loss	$ (132,738)	$ (68,523)	$ (48,079)
Denominator:			
Weighted average shares of common stock outstanding	32,909,762	28,102,386	21,415,733
Net loss per share, basic and diluted	$ (4.03)	$ (2.44)	$ (2.25)

The Company's potentially dilutive securities, which included stock options and RSUs, 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 shares of common stock excluded from the calculation of diluted net loss per share attributable to common stockholders for the years ended December 31, 2018, 2017 and 2016. All share amounts presented in the table below represent the total number outstanding as of December 31.

	December 31,		
	2018	2017	2016
Options to purchase common stock	4,282,081	3,328,757	1,738,524
Restricted stock unit awards	626,407	283,553	53,800
Total potential shares of common stock	4,908,488	3,612,310	1,792,324

12. Commitments and Contingencies

Agreements for Office Space

In November 2017, the Company entered into a sublease agreement with Auxilium Pharmaceuticals, LLC (the "Sublandlord") pursuant to which it subleases 33,019 square feet of office space for its headquarters in Wayne, Pennsylvania. Subject to the consent of Chesterbrook Partners, LP ("Landlord") as set forth in the lease by and between them and Sublandlord, the sublease has a term that runs through October 2023. If for any reason the lease between the Landlord and Sublandlord is terminated or expires prior to October 2023, the Company's sublease will automatically terminate.

In November 2016, the Company entered into a lease agreement with a third party for additional office space in Malvern, Pennsylvania with a term beginning in February 2017, and ending in November 2019. The Company also occupies office and laboratory space in St. Louis, Missouri under the terms of an agreement which expires in May 2019.

Rent expense was $886, $946 and $254 for the years ended December 31, 2018, 2017 and 2016, 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.

Capital Leases

Laboratory Equipment

The Company leases laboratory equipment which is used in its laboratory space in St. Louis, Missouri under two capital lease financing arrangements which the Company entered into in August 2017 and October 2017. The capital leases have terms which end in October 2020 and December 2020, respectively.

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Fleet Vehicles

The Company leases automobiles for its sales force and other field-based employees under the terms of a master lease agreement with a third party. The lease term for each automobile begins on the date the Company takes delivery and continues for a period of four years. The Company has accounted for the automobile leases as capital leases in its consolidated financial statements.

As of December 31, 2018, future minimum lease payments under operating and capital lease agreements were as follows:

Year Ending December 31,	
2019	$ 1,242
2020	1,156
2021	1,054
2022	791
2023	531
Total	$ 4,774

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 through March 2022, with such amounts being creditable against specified future payments.

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, 2018 or 2017.

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13. Income Taxes

The Tax Cuts and Jobs Act of 2017 (the "TCJA") was enacted on December 22, 2017 and became effective January 1, 2018. The TCJA made significant changes to U.S. tax law, including lowering U.S. corporate income tax rates, implementing a territorial tax system, imposing a one-time transition tax on deemed repatriated earnings of foreign subsidiaries and modifying the taxation of other income and expense items.

The TCJA reduced the U.S. corporate income tax rate from 35% to 21%, effective January 1, 2018. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to reverse. As a result of the reduction in the U.S. corporate income tax rate from 35% to 21% under the TCJA, the Company revalued its deferred tax liabilities, net as of December 31, 2017. The impact of revaluation of the deferred tax liabilities, net was $18,507 of income tax expense, which was more than offset by a reduction in the valuation allowance of $20,344 resulting in a net impact of a $1,837 tax benefit. The net tax benefit recorded was primarily the result of tax law changes which impacted the deferred tax liability the Company recorded for IPR&D related to the acquisition of Confluence. Under GAAP, IPR&D is an indefinite lived intangible that is capitalized on the balance sheet, but which does not have a cost basis under U.S. tax law.

The TCJA provided for a one-time transition tax on the deemed repatriation of post-1986 undistributed foreign subsidiary earnings and profits. The Company did not have consolidated accumulated earnings and profits attributable to its foreign subsidiary; accordingly, the Company did not record any income tax expense related to the transition tax.

Due to the timing of the enactment of the TCJA, the Staff of the SEC issued SAB 118 which provided a measurement period to report the impact of the TCJA. During the measurement period, provisional amounts for the effects of the law were able to be recorded to the extent a reasonable estimate can be made. To the extent that all information necessary is not available, prepared or analyzed, companies were able to recognize provisional estimated amounts for a period of up to one year following enactment of the TCJA. The Company completed its analysis during the year ended December 31, 2018, and made no adjustments as a result of TCJA under SAB 118.

During the years ended December 31, 2018, 2017 and 2016, the Company did not record an income tax benefit for net operating losses incurred in each year due to the uncertainty of realizing a benefit from those items.

Loss before income taxes is allocated as follows:

	Year Ended December 31,		
	2018	2017	2016
U.S. operations	$ (132,473)	$ (63,665)	$ (40,597)
Foreign operations	(265)	(6,688)	(7,482)
Loss before income taxes	$ (132,738)	$ (70,353)	$ (48,079)

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,		
	2018	2017	2016
Federal statutory income tax rate	(21.0) %	(34.0) %	(34.0) %
State taxes, net of federal benefit	(3.5)	(9.7)	(5.2)
Research and development tax credits	(2.1)	(1.1)	(2.0)
Permanent differences	0.8	0.4	1.8
Foreign rate differential	—	1.7	3.2
Change in deferred tax asset valuation allowance	25.7	17.4	36.2
Impact of U.S. tax reform	—	22.7	—
Effective income tax rate	(0.1) %	(2.6) %	— %

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Deferred tax liabilities, net as of December 31, 2018 and 2017 consisted of the following:

	December 31,	
	2018	2017
Deferred tax assets:		
Net operating loss carryforwards	$ 57,426	$ 26,566
Capitalized start-up costs	6,954	9,940
Research and development tax credit carryforwards	5,038	2,296
Capitalized research and development expenses	2,843	3,595
Stock based compensation expenses	9,037	6,220
Accrued compensation	923	—
Inventory	271	—
Property and equipment	—	86
Other	683	280
Total deferred tax assets	83,175	48,983
Deferred tax liabilities:		
Property and equipment	(674)	—
Intangible asset	(1,735)	(1,843)
Section 481(a) adjustment	—	(498)
Other	(330)	(313)
Total deferred tax liabilities	(2,739)	(2,654)
Valuation allowance	(80,985)	(46,878)
Deferred tax liabilities, net	$ (549)	$ (549)

As of December 31, 2018, the Company had federal and state net operating loss (“NOL”) carryforwards of $199,507 and $212,430, respectively, which begin to expire in 2032. As of December 31, 2018, the Company also had federal research and development tax credit carryforwards of $4,944 which begin to expire in 2032, and state research and development tax credit carryforwards of $118 which begin to expire in 2022. The Company also has $1,513 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 completed an analysis under Section 382 for NOLs generated from July 13, 2012 through December 31, 2016. Although the Company has experienced Section 382 ownership changes since 2012, the Company has concluded that it should have sufficient ability to utilize NOLs accumulated during the periods tested. The Company has not yet determined if a Section 382 ownership change has occurred during the years ended December 31, 2017 or 2018, or for Confluence prior to the acquisition. In addition, the Company may experience ownership changes in the future as a result of subsequent shifts in its stock ownership, some of which may be outside of the Company’s control.

The Company has evaluated the positive and negative evidence bearing upon its ability to realize the deferred tax assets. The Company considered its history of cumulative net losses incurred since inception, its lack of substantial revenue generated to date, and its forecasted future operating losses and concluded that it is more likely than not that the Company will not realize the benefits of its deferred tax assets. Accordingly, a full valuation allowance has been established against the deferred tax assets as of December 31, 2018 and 2017. The Company evaluates positive and negative evidence of its' ability to realize deferred tax assets at each reporting period.

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Changes in the valuation allowance for deferred tax assets during the years ended December 31, 2018, 2017, and 2016 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,		
	2018	2017	2016
Valuation allowance at beginning of year	$ (46,878)	$ (30,726)	$ (13,286)
Decreases recorded as benefit to income tax provision	—	—	—
Increases resulting from the acquisition of Confluence	—	(4,176)	—
Increases recorded to income tax provision	(34,107)	(11,976)	(17,440)
Valuation allowance as of end of year	$ (80,985)	$ (46,878)	$ (30,726)

During the year ended December 31, 2015, the Company recorded unrecognized tax benefits in the amount of $4,400 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. During the year ended December 31, 2017, the Company recorded uncertain tax benefits related to tax positions from the acquired Confluence business, which were settled during the year ended December 31, 2018. The following table summarizes the changes in the Company's unrecognized tax benefits:

	Year ended December 31,		
	2018	2017	2016
Unrecognized tax benefits at beginning of year	$ 43	$ —	$ (4,400)
Increases related to prior year tax provisions	—	43	—
Decreases related to prior year tax provisions	(43)	—	4,400
Increases related to current year tax provisions	—	—	—
Unrecognized tax benefits as of end of year	$ —	$ 43	$ —

The total amount of unrecognized tax benefits that, if recognized, would impact the Company's effective tax rate were $0 and $36 as of December 31, 2018 and 2017, respectively. The Company accrues interest and penalties related to unrecognized tax benefits in income tax expense (benefit) in the consolidated statement of operations and comprehensive loss. During each of the years ended December 31, 2018, 2017 and 2016, the Company recognized expense (benefit) of $0, $3 and $0, respectively, 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.

14. Related Party Transactions

In August 2013, the Company entered into a sublease agreement with NeXeption, Inc. ("NeXeption"), which was subsequently assigned to NST Consulting, LLC, a wholly-owned subsidiary of NST, LLC. In November 2017, the Company terminated the sublease with NST Consulting, LLC effective March 31, 2018. The Company paid $590 to NST Consulting, LLC, which amount represented accelerated rent payments. The Company recorded a one-time charge of $506 in the year ended December 31, 2017 which is included in general and administrative expenses in the consolidated statement of operations. Total payments made under the sublease during the years ended December 31, 2018, 2017 and 2016, were $570, $318 and $253, respectively.

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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. The NST Services agreement was subsequently assigned by NST, LLC to NST Consulting, LLC. Under the same agreement the Company also provided services to another company under common control with the Company and NST Consulting, LLC and was reimbursed by NST, LLC for those services. In November 2017, the Company terminated the NST Services Agreement effective December 31, 2017.

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, and three of the Company's executive officers are and have been members of entities affiliated with NST, LLC.

During the years ended December 31, 2018, 2017 and 2016 amounts included in the consolidated statement of operations for the NST Services Agreement are summarized in the following table:

	Year Ended December 31,		
	2018	2017	2016
Services provided by NST Consulting, LLC	$ —	$ 225	$ 323
Services provided to NST Consulting, LLC	—	(17)	(56)
General and administrative expense, net	$ —	$ 208	$ 267
Services provided by NST Consulting, LLC	$ —	$ —	$ 246
Services provided to NST Consulting, LLC	—	—	(97)
Research and development expense, net	$ —	$ —	$ 149
Services provided by NST Consulting, LLC	$ —	$ 225	$ 569
Services provided to NST Consulting, LLC	—	(17)	(153)
Total, net	$ —	$ 208	$ 416
Net payments made to NST Consulting, LLC	$ —	$ 300	$ 325

The Company had a net amount payable of $0 and $570 due to NST Consulting, LLC under the NST Services Agreement as of December 31, 2018, and December 31, 2017, respectively.

15. Agreements Related to Intellectual Property

License, Development and Commercialization Agreement with Cipher Pharmaceuticals Inc.

In April 2018, the Company entered into an exclusive license agreement with Cipher Pharmaceuticals Inc. (“Cipher”) for the rights to obtain regulatory approval of and commercialize A-101 40% Topical Solution, which the Company markets under the brand name ESKATA in the United States, in Canada for the treatment of SK. Under the agreement, Cipher is responsible for obtaining marketing approval in Canada for A-101 40% Topical Solution. The Company will supply Cipher with finished product, and, if regulatory approval is obtained, Cipher will be responsible for distribution and commercialization of A-101 40% Topical Solution in Canada. Additionally, Cipher is responsible for all expenses related to regulatory and commercial activities for A-101 40% Topical Solution in Canada. The Company received an upfront payment of $1,000 upon signing of the agreement with Cipher and $500 upon the achievement of a specified regulatory milestone, both of which are included in other revenue in the Company’s consolidated statement of operations for the year ended December 31, 2018. The Company can earn a remaining payment of $500 upon the achievement of a specified regulatory milestone, and aggregate payments of $1,750 upon the achievement of specified commercial milestones under the terms of the agreement with Cipher. Cipher will also be required to pay the Company a low double-digit percentage royalty on net sales of A-101 40% Topical Solution in Canada. The term of the agreement expires on the later of the expiration of applicable patents in Canada or the 15th anniversary of the first commercial sale of

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licensed product in Canada. Cipher submitted a New Drug Submission for A-101 40% Topical Solution for the treatment of raised SKs, which was accepted for review by Health Canada in December 2018.

Assignment Agreement with Estate of Mickey Miller and Finder's Services Agreement with KPT Consulting, LLC

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 ESKATA and A-101 45% Topical Solution. 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 finder's services agreement, the Company made one-time milestone payments of $300 in the year ended December 31, 2016 upon the dosing of the first human subject with ESKATA in the Company's Phase 3 clinical trial, $1,000 in the year ended December 31, 2017 upon the achievement of a specified regulatory milestone and $1,500 in the year ended December 31, 2018 upon the achievement of a specified commercial milestone. The payments were recorded as general and administrative expenses in the Company's consolidated statement of operations.

Under the finder's services agreement the Company is obligated to make an additional milestone payment of $3,000 upon the achievement of a specified commercial milestone. Under each of the assignment agreement and the finder's services agreement, the Company is obligated to pay royalties on sales of ESKATA and any related products, at low single-digit percentages of net sales, subject to reduction in specified circumstances. The Company incurred an aggregate expense of $112 and $0 related to royalty payments under these agreements during the years ended December 31, 2018 and 2017, respectively. 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 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 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

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Company expensed the cost of the acquired intellectual property as of the acquisition date on the basis that the cost of intellectual property that is purchased for use in research and development activities, and that has no alternative future uses, is expensed when acquired.

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

In March 2016, the Company entered into a stock purchase agreement (the "Vixen Agreement") with Vixen, JAK1, LLC, JAK2, LLC and JAK3, LLC (together, the "Selling Stockholders") and Shareholder Representative Services LLC, 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. Following the acquisition of Vixen, 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 each year through March 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 (as amended, 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.

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 intellectual property purchased for use in research and development activities, and that has no alternative future uses, is expensed when acquired. 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.

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16. Retirement 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 $662, $270, and $176 for the years ended December 31, 2018, 2017 and 2016, respectively.

17. Segment Information

The Company has two reportable segments, dermatology therapeutics and contract research. The dermatology therapeutics segment is focused on identifying, developing and commercializing innovative therapies to address significant unmet needs for dermatological and immuno-inflammatory diseases. The Company currently markets and sells two drugs, ESKATA and RHOFADE. ESKATA is a proprietary formulation of high-concentration hydrogen peroxide topical solution that the Company is commercializing as an office-based prescription treatment for raised SKs, a common non-malignant skin tumor. RHOFADE is approved for the topical treatment of persistent facial erythema, or redness, associated with rosacea in adults. The Company sells ESKATA and RHOFADE to a limited number of wholesalers in the U.S. These wholesalers subsequently resell the Company's products to pharmacies and health care providers. The contract research segment earns revenue from the provision of laboratory services to clients through Confluence, the Company's wholly-owned subsidiary. Contract research revenue is generally evidenced by contracts with clients which are on an agreed upon fixed-price, fee-for-service basis. Corporate and other includes general and administrative expenses as well as eliminations of intercompany transactions. The Company does not report balance sheet information by segment since it is not reviewed by the chief operating decision maker, and all of the Company's tangible assets are held in the United States.

The Company's results of operations by segment for the years ended December 31, 2018, 2017 and 2016 are summarized in the tables below:

Year Ended December 31, 2018	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company

Revenue, net	$ 5,441	$ 13,134	$ (8,484)	$ 10,091
Cost of revenue	2,522	11,398	(7,070)	6,850
Research and development	64,423	—	(1,414)	63,009
Sales and marketing	47,957	40	—	47,997
General and administrative	30	2,141	25,478	27,649
Loss from operations	$ (109,491)	$ (445)	$ (25,478)	$ (135,414)

Year Ended December 31, 2017	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ 3,202	$ (1,519)	$ 1,683
Cost of revenue	—	2,726	(1,519)	1,207
Research and development	39,790	—	—	39,790
Sales and marketing	13,769	—	—	13,769
General and administrative	222	673	18,445	19,340
Loss from operations	$ (53,781)	$ (197)	$ (18,445)	$ (72,423)

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Year Ended December 31, 2016	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ —	$ —	$ —
Cost of revenue	—	—	—	—
Research and development	33,476	—	—	33,476
Sales and marketing	3,295	—	—	3,295
General and administrative	155	—	11,641	11,796
Loss from operations	$ (36,926)	$ —	$ (11,641)	$ (48,567)

Intersegment Revenue

Revenue for the contract research segment included $8,484 and $1,519 for services performed on behalf of the dermatology therapeutics segment for the years ended December 31, 2018 and 2017, respectively. All intersegment revenue has been eliminated in the Company's consolidated statement of operations.

18. Quarterly Financial Information (unaudited)

The following table summarizes the unaudited consolidated financial results of operations for the quarters indicated:

	2018 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue, net	$ 1,118	$ 3,676	$ 1,628	$ 3,669
Gross profit	151	2,495	435	160
Operating expenses	31,099	34,473	33,885	39,198
Other income, net	719	760	710	487
Net loss	(30,229)	(31,218)	(32,740)	(38,551)
Net loss per share, basic and diluted	$ (0.98)	$ (1.01)	$ (1.06)	$ (0.99)

	2017 Quarter Ended			
	March 31,	June 30,	September 30,	December 31,
Revenue, net	$ —	$ —	$ 684	$ 999
Gross profit	—	—	231	245

Operating expenses	12,930	15,295	18,987	25,687
Other income, net	371	457	564	678
Net loss	(12,559)	(14,838)	(18,192)	(22,934)
Net loss per share, basic and diluted	$ (0.48)	$ (0.56)	$ (0.63)	$ (0.74)

Net loss per share is computed independently for each quarter and, therefore, the sum of the quarterly per share amounts may not equal the year-to-date per share amount.

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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, 2018, 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 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, 2018, 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 Rules 13a-15(d) and 15d-15(d) of the Exchange Act that occurred during the quarter ended December 31, 2018 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 Rule 13a-15(f) of the Exchange Act. 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, 2018, 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(b) 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 2019 Annual Meeting of Stockholders, or the 2019 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 2019 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 2019 Proxy Statement under the captions “Information Regarding the Board of Directors and Corporate Governance,” “Election of Directors,” “Executive Officers Who Are Not Directors” 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 2019 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 2019 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 2019 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 2019 Proxy Statement under the caption “Ratification of Selection of Independent Registered Public Accounting Firm.”

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PART IV

Item 15. Exhibits and Financial Statement Schedules.

(a)The following documents are filed as part of this report:

(1)Financial Statements

Our consolidated financial statements are listed in the "Index to Consolidated Financial Statements" under Part II. Item 8 of this Annual Report on Form 10 K.

(2)Financial Statement Schedules

Financial statement schedules have been omitted in this report because they are not applicable, not required under the instructions, or the information required is set forth in the consolidated financial statements or related notes thereto.

(3)Exhibits

See exhibits listed under part (b) below.

(b)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).
2.2#	Agreement and Plan of Merger, dated as of August 3, 2017, by and among the Registrant, Aclaris Life Sciences, Inc., Confluence Life Sciences, Inc. and Fortis Advisors LLC (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 November 7, 2017).
2.3#	Asset Purchase Agreement, by and between the Registrant and Allergan Sales, LLC, dated as of October 15, 2018, as amended on November 30, 2018 (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 December 3, 2018).

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#	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).
10.3	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).

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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 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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10+	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).
10.11+*	Form of Performance Stock Option Grant Notice and Stock Option Agreement used in connection with the 2015 Equity Incentive Plan.
10.12+*	Form of Performance Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement used in connection with the 2015 Equity Incentive Plan.
10.13	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).
10.14+	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).
10.15*+	Amended & Restated Non-Employee Director Compensation Policy.
10.16#	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).
10.17+	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).
10.18+	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).
10.19+	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).
10.20+	Employment Agreement with Kamil Ali-Jackson, dated as of September 17, 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 9, 2017).
10.21#	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).
10.22#	First Amendment to License Agreement, by and between The Trustees of Columbia University in the City of New York and the Registrant, dated as of June 27, 2018 (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 August 3, 2018).
10.23+	Aclaris Therapeutics, Inc. Inducement Plan (incorporated herein 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 August 1, 2017).

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10.24+	Form of Stock Option Grant Notice and Stock Option Agreement used in connection with the Aclaris Therapeutics, Inc. Inducement Plan (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on August 1, 2017).
10.25+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement used in connection with the Aclaris Therapeutics, Inc. Inducement Plan (incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on August 1, 2017).
10.26	Sublease, dated November 2, 2017, by and between the Registrant and Auxilium Pharmaceuticals, 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, 2017).
10.27*	First Amendment to Sublease, dated as of December 13, 2017, by and between the Registrant and Auxilium Pharmaceuticals, LLC.
10.28#	Commercial Supply Manufacturing Services Agreement, by and between the Registrant and James Alexander Corporation, dated as of January 24, 2018 (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 8, 2018).
10.29#	Distribution Agreement, by and between the Registrant and McKesson Specialty Care Distribution Corporation, dated as of October 13, 2017, as amended by Amendment No. 1, dated as of March 6, 2018 (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 August 3, 2018).
10.30#	Exclusive Patent License Agreement, by and between the Registrant and Allergan, Inc., dated as of November 30, 2018 (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 December 3, 2018).
10.31^*	Loan and Security Agreement, dated as of October 15, 2018, by and among Oxford Finance LLC, the lenders party thereto, the Registrant, Confluence Discovery Technologies, Inc. and Aclaris Life Sciences, Inc., as amended by First Amendment to Loan and Security Agreement, dated as of January 28, 2019.
21.1*	Subsidiaries of the Registrant.
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.
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.

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

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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
18, 2019

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 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 18, 2019
/s/ Frank Ruffo Frank Ruffo	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	March 18, 2019
/s/ Stephen A. Tullman	Chairman of the Board of Directors	

Stephen A. Tullman		March 18, 2019
/s/ Christopher Molineaux Christopher Molineaux	Director	March 18, 2019
/s/ Anand Mehra, M.D. Anand Mehra, M.D.	Director	March 18, 2019
/s/ William Humphries William Humphries	Director	March 18, 2019
/s/ Andrew Powell Andrew Powell	Director	March 18, 2019
/s/ Andrew Schiff Andrew Schiff	Director	March 18, 2019
/s/ Bryan Reasons Bryan Reasons	Director	March 18, 2019