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UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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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,” “predict,” “project,” “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 RHOFADÉ 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 RHOFADÉ 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.

All brand names or trademarks appearing in this Annual Report, including ESKATA, ESKERIELE, RHOFADÉ, 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 its 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 RHOFADÉ (oxymetazoline hydrochloride) cream, 1%, or RHOFADÉ, which includes an exclusive license to certain intellectual property for RHOFADÉ, as well as additional intellectual property, from Allergan Sales, LLC, or Allergan. RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ 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.

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 RHOFADÉ 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 immunoinflammatory diseases. Our pipeline of drug candidates is summarized in the table below:

Program	Indication(s)	Preclinical	Phase 1	Phase 2	Phase 3
A-101(45%) Topical	Common Warts				
ATI-502 JAK1/JAK3 Inhibitor Topical	Alopecia Areata				
	Vitiligo				
	Androgenetic Alopecia				
	Atopic Dermatitis				
ATI-501 JAK1/JAK3 Inhibitor Oral	Alopecia Areata				
ATI-450 MK-2 Pathway Inhibitor Oral	RA, Psoriasis, Hidradenitis Suppurativa, CAPS, Pyoderma Gangrenosum, Other				
ATI-1777 JAK1/JAK3 Inhibitor Soft Topical	Atopic dermatitis, Vitiligo, Alopecia Areata				
ITK/JAK3 Inhibitor Soft Topical	Psoriasis, Inflammatory Dermatoses				
ITK/JAK3 Inhibitor Oral	Psoriasis, Inflammatory Dermatoses				
MK-2 Pathway Inhibitor Oral	Oncology				
ITK/JAK3 Inhibitor Oral, gut-restricted	Ulcerative colitis / Crohn's disease				

**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.

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.

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:

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

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

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 RHOFADÉ.

### **Commercialization**

We are commercializing ESKATA and RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ in the United States in December 2018. We currently rely on Allergan to distribute RHOFADÉ 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 RHOFADÉ in the United States. We sell RHOFADÉ 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 RHOFADÉ. We have no sales of RHOFADÉ 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

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; Skinciential 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 RHOFADÉ 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, RHOFADÉ 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

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 RHOFADÉ, 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 RHOFADÉ, 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 RHOFADÉ, 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 RHOFADÉ, 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,

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.

## 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.

### ***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.

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 RHOFADÉ, which includes an exclusive license to certain intellectual property for RHOFADÉ, 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 RHOFADÉ, 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.

## **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

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.

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

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.

## **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 State 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, RHOFADÉ 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.

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

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.

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 replace 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

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

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 RHOFAGE, 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 RHOFAGE 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.

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](http://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.

## 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 RHOFADÉ, 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 RHOFADÉ 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.

For ESKATA, RHOFADÉ 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 RHOFADÉ and conduct clinical trials of and seek marketing approval for our drug candidates. In addition, ESKATA and RHOFADÉ, 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.

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 RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ, 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

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

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 RHOFADÉ which are based on contractual percentages applied to the amount of RHOFADÉ 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 RHOFADÉ. 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 RHOFADÉ 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.

## 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.

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.

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

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.

***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, RHOFADÉ and Our Drug Candidates**

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

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

To achieve commercial success for ESKATA and RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ, 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

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 RHOFADÉ 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, RHOFADÉ or any other drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than we may obtain approval for our drug candidates, which could result in our competitors establishing a strong market position before we are able to enter the market.

Many of the companies against which we are competing, or against which we may compete in the future, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical 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 RHOFADÉ 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 RHOFADÉ, 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 RHOFADÉ 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.

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 RHOFAD. 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.

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 RHOFADÉ 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 RHOFADÉ 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, RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ, 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.

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 RHOFADÉ;
- the possible increase in costs by our manufacturers for the finished dosage forms of ESKATA and RHOFADÉ; 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 RHOFADÉ.

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.

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

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

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 adrenoceptor agonists, which cover the approved use of RHOFADÉ, expire between January 2024 and May 2028. The issued U.S. patent that covers cream formulations of oxymetazoline, including RHOFADÉ, 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 RHOFADÉ 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

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 RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ. This patent family is also subject to an exclusive license granted by Allergan to a third party, which places 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.

***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 RHOFADÉ, 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 RHOFADÉ 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 RHOFADÉ, 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 RHOFADÉ

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.

***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

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, RHOFADÉ, 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 RHOFADÉ 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 RHOFADÉ, 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 RHOFADÉ. We are aware that a third party generic pharmaceutical company completed a Phase 3 clinical trial in March 2018 evaluating the reduction in erythema in adults with moderate to severe facial erythema associated with rosacea with a 1% oxymetazoline topical cream in comparison to an oxymetazoline reference listed drug. Such a clinical trial could serve as the basis for filing an ANDA or 505(b)(2)

application for a generic of RHOFADÉ 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 RHOFADÉ 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

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, RHOFADÉ 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

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.

***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 RHOFADÉ 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, RHOFADÉ 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, RHOFADÉ 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, RHOFADÉ 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.

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;

- 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

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

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 RHOFAD 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,

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.

***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

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

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.

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 RHOFADÉ.***

The success of our acquisition of RHOFADÉ will depend, in large part, on our ability to realize operating synergies from combining RHOFADÉ 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 RHOFADÉ;
- 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 RHOFADÉ 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 RHOFADÉ.

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

- conditions or trends in our industry;
- changes in the 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

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 66<sup>2/3</sup>% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

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

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

Our executive officers, directors and current beneficial owners of 5% or more of our common stock and their respective affiliates beneficially own a substantial portion of our common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets, or other significant corporate transactions. The interests of this group of stockholders may not coincide with our interests or the interests of other stockholders.

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

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

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

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of (1) December 31, 2020, (2) the last day of the fiscal year in which we have total annual gross revenue of at least \$1.07 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.

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 RHOFADÉ, 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.

***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.

**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.

## 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.

## 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 RHOFADÉ (oxymetazoline hydrochloride) cream, 1%, or RHOFADÉ, which includes an exclusive license to certain intellectual property for RHOFADÉ, as well as additional intellectual property, from Allergan Sales, LLC, or Allergan. RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ 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.

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 RHOFADÉ. In addition, ESKATA and RHOFADÉ, 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.

## **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

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 15<sup>th</sup> 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 RHOFADÉ, which includes an exclusive license to certain intellectual property for RHOFADÉ, 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 RHOFADÉ, 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.

RHOFADÉ 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.

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 RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ in the United States in December 2018. We currently rely on Allergan to distribute RHOFADÉ 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 RHOFADÉ in the United States. We sell RHOFADÉ 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 RHOFADÉ. We have no sales of RHOFADÉ 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.

## **Cost of Revenue**

Cost of revenue consists of the cost of manufacturing the finished product forms of ESKATA and RHOFADÉ, 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 RHOFADÉ;
- 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 RHOFADÉ inventory; and
- non-cash amortization of the intangible asset related to RHOFADÉ 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

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 RHOFADÉ 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.

## **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.

*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 RHOFADÉ, 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.

## **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 RHOFAD. 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

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.

**Results of Operations****Comparison of Years Ended December 31, 2018 and 2017**

	<u>Year Ended December 31,</u>		<u>Change</u>
	<u>2018</u>	<u>2017</u>	
	(In thousands)		
<b>Revenues:</b>			
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
<b>Operating expenses:</b>			
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	<u>\$ (132,738)</u>	<u>\$ (68,523)</u>	<u>\$ (64,215)</u>

**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 RHOFADÉ, respectively, during the year ended December 31, 2018. We acquired RHOFADÉ 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 RHOFADÉ product sales, net, respectively. Cost of revenue included \$0.6 million of non-cash amortization related to the intangible asset for the RHOFADÉ 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.

## Research and Development Expenses

The following table summarizes our research and development expenses:

	Year Ended December 31,		Change
	2018	2017	
	(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	<u>\$ 63,009</u>	<u>\$ 39,790</u>	<u>\$ 23,219</u>

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,		Change
	2018	2017	
	(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	<u>\$ 47,997</u>	<u>\$ 13,769</u>	<u>\$ 34,228</u>

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.

**General and Administrative Expenses**

The following table summarizes our general and administrative expenses:

	Year Ended December 31,		Change
	2018	2017	
	(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.

**Comparison of Years Ended December 31, 2017 and 2016**

	Year Ended December 31,		Change
	2017	2016	
	(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	<u>\$ (68,523)</u>	<u>\$ (48,079)</u>	<u>\$ (20,444)</u>

**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,		Change
	2017	2016	
	(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	<u>\$ 39,790</u>	<u>\$ 33,476</u>	<u>\$ 6,314</u>

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,		Change
	2017	2016	
	(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
<b>Total research and development expenses</b>	<b>\$ 13,769</b>	<b>\$ 3,295</b>	<b>\$ 10,474</b>

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,		Change
	2017	2016	
	(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
<b>Total general and administrative expenses</b>	<b>\$ 19,340</b>	<b>\$ 11,796</b>	<b>\$ 7,544</b>

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.

### **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.

### **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

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 copy assistance and commercial rebates related to sales of RHOFADÉ 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 RHOFADÉ 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.

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 RHOFAD, 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 RHOFAD 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 RHOFAD, 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

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 RHOFADÉ, 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 RHOFADÉ, 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 RHOFADÉ, 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.

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 RHOFADÉ 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 RHOFADÉ 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 RHOFADÉ 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	—	—
<b>Total</b>	<b>\$ 35,175</b>	<b>\$ 1,343</b>	<b>\$ 5,800</b>	<b>\$ 28,032</b>	<b>\$ —</b>

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.

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 RHOFADÉ 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 RHOFADÉ, 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.

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

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.

**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.

**Item 8. Financial Statements and Supplementary Data**

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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.

**ACLARIS THERAPEUTICS, INC.**  
**CONSOLIDATED BALANCE SHEETS**

(In thousands, except share and per share data)

	December 31,	
	2018	2017
<b>Assets</b>		
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	<u>\$ 275,566</u>	<u>\$ 243,509</u>
<b>Liabilities and Stockholders' Equity</b>		
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
<b>Stockholders' Equity:</b>		
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	<u>\$ 275,566</u>	<u>\$ 243,509</u>

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

**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
<b>Revenues:</b>			
Product sales, net	\$ 3,940	\$ —	\$ —
Contract research	4,651	1,683	—
Other revenue	1,500	—	—
<b>Total revenue, net</b>	<b>10,091</b>	<b>1,683</b>	<b>—</b>
Cost of revenue	6,850	1,207	—
<b>Gross profit</b>	<b>3,241</b>	<b>476</b>	<b>—</b>
<b>Operating expenses:</b>			
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
<b>Total operating expenses</b>	<b>138,655</b>	<b>72,899</b>	<b>48,567</b>
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)	—
<b>Net loss</b>	<b>\$ (132,738)</b>	<b>\$ (68,523)</b>	<b>\$ (48,079)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (4.03)</b>	<b>\$ (2.44)</b>	<b>\$ (2.25)</b>
<b>Weighted average common shares outstanding, basic and diluted</b>	<b>32,909,762</b>	<b>28,102,386</b>	<b>21,415,733</b>
<b>Other comprehensive income (loss):</b>			
Unrealized gain (loss) on marketable securities, net of tax of \$0	\$ 145	\$ (121)	\$ 105
Foreign currency translation adjustments	32	144	(225)
<b>Total other comprehensive income (loss)</b>	<b>177</b>	<b>23</b>	<b>(120)</b>
<b>Comprehensive loss</b>	<b>\$ (132,561)</b>	<b>\$ (68,500)</b>	<b>\$ (48,199)</b>

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

**ACLARIS THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY**

(In thousands, except share data)

	Common Stock	Additional	Accumulated	Accumulated	Total	
	Shares	Par Value	Paid-in Capital	Other Comprehensive Loss	Deficit	Stockholders' Equity
<b>Balance at December 31, 2015</b>	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)
<b>Balance at December 31, 2016</b>	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)
<b>Balance at December 31, 2017</b>	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)
<b>Balance at December 31, 2018</b>	41,210,725	\$ —	\$ 507,366	\$ (69)	\$ (292,173)	\$ 215,124

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

**ACLARIS THERAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF CASH FLOWS**

(In thousands)

	Year Ended December 31,		
	2018	2017	2016
<b>Cash flows from operating activities:</b>			
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	<u>(100,811)</u>	<u>(54,663)</u>	<u>(34,603)</u>
<b>Cash flows from investing activities:</b>			
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	<u>9,367</u>	<u>(55,692)</u>	<u>(61,903)</u>
<b>Cash flows from financing activities:</b>			
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	<u>128,261</u>	<u>100,386</u>	<u>116,826</u>
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	<u>\$ 57,019</u>	<u>\$ 20,202</u>	<u>\$ 30,171</u>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>			
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.

**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, RHOFADÉ (oxymetazoline hydrochloride) cream, 1% (“RHOFADÉ”) (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 RHOFADÉ 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.

## **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 RHOFADÉ 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

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.

### **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.

## **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 RHOFADÉ. 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.

### **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

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.

### **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.

## 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

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	\$	<u>67,122</u>

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

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 RHOFADÉ 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 RHOFADÉ are based on estimates of fair value using assumptions that the Company believes is reasonable. The Company accounted for the acquisition of RHOFADÉ as an asset acquisition because substantially all of the fair value of the assets acquired is concentrated in a single asset, the RHOFADÉ 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 RHOFADÉ:

Inventory	\$	893
Intangible assets, net		66,229
Total assets acquired	\$	<u>67,122</u>

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 RHOFADÉ 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 RHOFADÉ. In addition, the 10-year useful life is based upon expiration dates of key patents underlying the RHOFADÉ 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	\$	<u>24,322</u>

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		<u>18,504</u>
Total assets acquired		27,437
Accounts payable and accrued expenses		656
Deferred tax liability		2,386

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.

	2018	Year Ended December 31, 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.

**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
<b>Assets:</b>				
Cash equivalents	\$ 49,766	\$ 4,992	\$ —	\$ 54,758
Marketable securities	—	110,953	—	110,953
<b>Total Assets</b>	<b>\$ 49,766</b>	<b>\$ 115,945</b>	<b>\$ —</b>	<b>\$ 165,711</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 934	\$ 934
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 934</b>	<b>\$ 934</b>
	December 31, 2017			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Cash equivalents	\$ 19,339	\$ —	\$ —	\$ 19,339
Marketable securities	—	188,652	—	188,652
<b>Total Assets</b>	<b>\$ 19,339</b>	<b>\$ 188,652</b>	<b>\$ —</b>	<b>\$ 207,991</b>
<b>Liabilities:</b>				
Acquisition-related contingent consideration	\$ —	\$ —	\$ 4,378	\$ 4,378
<b>Total liabilities</b>	<b>\$ —</b>	<b>\$ —</b>	<b>\$ 4,378</b>	<b>\$ 4,378</b>

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.

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			Fair Value
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	
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	<u>\$ 110,978</u>	<u>\$ —</u>	<u>\$ (25)</u>	<u>\$ 110,953</u>

  

	December 31, 2017			Fair Value
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	
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	<u>\$ 188,822</u>	<u>\$ —</u>	<u>\$ (170)</u>	<u>\$ 188,652</u>

## 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	<u>\$ 4,280</u>	<u>\$ 2,159</u>

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

## 6. Intangible Assets

Intangible assets consisted of the following:

	Remaining Life	Gross Cost		Accumulated Amortization	
		December 31,		December 31,	
		2018	2017	2018	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

## **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.

### **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.

## 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.

**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 <sup>(1)</sup>	\$ 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.

### 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	<u>626,407</u>	\$ 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	<u>\$ 20,055</u>	<u>\$ 14,430</u>	<u>\$ 6,104</u>

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.

## 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
<b>Numerator:</b>			
Net loss	\$ (132,738)	\$ (68,523)	\$ (48,079)
<b>Denominator:</b>			
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.

### *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:

<b>Year Ending December 31,</b>	
2019	\$ 1,242
2020	1,156
2021	1,054
2022	791
2023	531
Total	<u>\$ 4,774</u>

### **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.

### 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:

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

A reconciliation of the U.S. federal statutory income tax rate to the Company's effective income tax rate is as follows:

	<u>Year Ended December 31,</u>		
	<u>2018</u>	<u>2017</u>	<u>2016</u>
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	<u>(0.1)%</u>	<u>(2.6)%</u>	<u>— %</u>

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 carryforwards 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.

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	<u>\$ (80,985)</u>	<u>\$ (46,878)</u>	<u>\$ (30,726)</u>

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	<u>\$ —</u>	<u>\$ 43</u>	<u>\$ —</u>

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.

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 NeXption 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	<u>\$ —</u>	<u>\$ 208</u>	<u>\$ 267</u>
Services provided by NST Consulting, LLC	\$ —	\$ —	\$ 246
Services provided to NST Consulting, LLC	—	—	(97)
Research and development expense, net	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 149</u>
Services provided by NST Consulting, LLC	\$ —	\$ 225	\$ 569
Services provided to NST Consulting, LLC	—	(17)	(153)
Total, net	<u>\$ —</u>	<u>\$ 208</u>	<u>\$ 416</u>
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 15<sup>th</sup> 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.

#### **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

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.

## 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 RHOFADÉ. 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. RHOFADÉ is approved for the topical treatment of persistent facial erythema, or redness, associated with rosacea in adults. The Company sells ESKATA and RHOFADÉ 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:

	Dermatology	Contract	Corporate	Total
<b><u>Year Ended December 31, 2018</u></b>	<b><u>Therapeutics</u></b>	<b><u>Research</u></b>	<b><u>and Other</u></b>	<b><u>Company</u></b>
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)

	Dermatology	Contract	Corporate	Total
<b><u>Year Ended December 31, 2017</u></b>	<b><u>Therapeutics</u></b>	<b><u>Research</u></b>	<b><u>and Other</u></b>	<b><u>Company</u></b>
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)

	Dermatology Therapeutics	Contract Research	Corporate and Other	Total Company
<b>Year Ended December 31, 2016</b>				
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.

## **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.

### **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.”

**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#	<a href="#">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).</a>
2.2#	<a href="#">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).</a>
2.3#	<a href="#">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).</a>
3.1	<a href="#">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).</a>
3.2	<a href="#">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).</a>
4.1	<a href="#">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).</a>
10.1#	<a href="#">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).</a>
10.2#	<a href="#">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).</a>
10.3	<a href="#">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).</a>

- 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\).](#)

10.24+	<a href="#">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).</a>
10.25+	<a href="#">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).</a>
10.26	<a href="#">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).</a>
10.27*	<a href="#">First Amendment to Sublease, dated as of December 13, 2017, by and between the Registrant and Auxilium Pharmaceuticals, LLC.</a>
10.28#	<a href="#">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).</a>
10.29#	<a href="#">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).</a>
10.30#	<a href="#">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).</a>
10.31^*	<a href="#">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.</a>
21.1*	<a href="#">Subsidiaries of the Registrant.</a>
23.1*	<a href="#">Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.</a>
24.1*	<a href="#">Power of Attorney (contained on signature page hereto).</a>
31.1*	<a href="#">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.</a>
31.2*	<a href="#">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.</a>
32.1 *†	<a href="#">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.</a>
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.

**Item 16. Form 10-K Summary.**

Not applicable.



**ACLARIS THERAPEUTICS, INC.  
2015 EQUITY INCENTIVE PLAN**

**STOCK OPTION GRANT NOTICE**

Aclaris Therapeutics, Inc. (the “*Company*”), pursuant to its 2015 Equity Incentive Plan (the “*Plan*”), hereby grants to Optionholder an option to purchase the number of shares of the Company’s Common Stock set forth below. This option is subject to all of the terms and conditions as set forth in this notice, in the Option Agreement, the Plan and the Notice of Exercise, all of which are attached hereto and incorporated herein in their entirety. Capitalized terms not explicitly defined herein but defined in the Plan or the Option Agreement will have the same definitions as in the Plan or the Option Agreement. If there is any conflict between the terms in this notice and the Plan, the terms of the Plan will control.

Optionholder:	_____
Date of Grant:	_____
Vesting Commencement Date:	_____
Number of Shares Subject to Option:	_____
Exercise Price (Per Share):	_____
Total Exercise Price:	_____
Expiration Date:	_____

**Type of Grant:**     Incentive Stock Option<sup>1</sup>             Nonstatutory Stock Option

**Exercise Schedule:** Same as Vesting Schedule

**Vesting Schedule:** [\_\_\_\_\_], subject to Optionholder’s Continuous Service through each such date.

**Termination:**    Notwithstanding anything to the contrary in this Stock Option Grant Notice or the Option Agreement, if the [PERFORMANCE CONDITION] is not achieved by [DATE], then the shares of Common Stock subject to this option shall not vest, this option shall terminate on [DATE] and Optionholder shall have no further right, title or interest in this option or the shares of Common Stock subject to this option.

**Payment:**        By one or a combination of the following items (described in the Option Agreement):

- By cash, check, bank draft or money order payable to the Company
- Pursuant to a Regulation T Program if the shares are publicly traded
- By delivery of already-owned shares if the shares are publicly traded
- If and only to the extent this option is a Nonstatutory Stock Option, and subject to the Company’s consent at the time of exercise, by a “net exercise” arrangement

**Additional Terms/Acknowledgements:** Optionholder acknowledges receipt of, and understands and agrees to, this Stock Option Grant Notice, the Option Agreement and the Plan. Optionholder acknowledges and agrees that this Stock Option Grant Notice and the Option Agreement may not be modified, amended

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<sup>1</sup> If this is an Incentive Stock Option, it (plus other outstanding Incentive Stock Options) cannot be first *exercisable* for more than \$100,000 in value (measured by exercise price) in any calendar year. Any excess over \$100,000 is a Nonstatutory Stock Option.

or revised except as provided in the Plan. Optionholder further acknowledges that as of the Date of Grant, this Stock Option Grant Notice, the Option Agreement, and the Plan set forth the entire understanding between Optionholder and the Company regarding this option award and supersede all prior oral and written agreements, promises and/or representations on that subject with the exception of (i) options previously granted and delivered to Optionholder, (ii) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law and (iii) any written employment or severance arrangement that would provide for vesting acceleration of this option upon the terms and conditions set forth therein.

By accepting this option, Optionholder consents to receive such documents by electronic delivery and to participate in the Plan through an online or electronic system established and maintained by the Company or another third party designated by the Company.

**ACLARIS THERAPEUTICS, INC.**

**OPTIONHOLDER:**

By: \_\_\_\_\_  
Signature

\_\_\_\_\_ Signature

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**ATTACHMENTS:** Option Agreement, 2015 Equity Incentive Plan and Notice of Exercise

**ATTACHMENT I**  
**OPTION AGREEMENT**

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**ACLARIS THERAPEUTICS, INC.  
2015 EQUITY INCENTIVE PLAN**

**OPTION AGREEMENT  
(INCENTIVE STOCK OPTION OR NONSTATUTORY STOCK OPTION)**

Pursuant to your Stock Option Grant Notice (“*Grant Notice*”) and this Option Agreement, Aclaris Therapeutics, Inc. (the “*Company*”) has granted you an option under its 2015 Equity Incentive Plan (the “*Plan*”) to purchase the number of shares of the Company’s Common Stock indicated in your Grant Notice at the exercise price indicated in your Grant Notice. The option is granted to you effective as of the date of grant set forth in the Grant Notice (the “*Date of Grant*”). If there is any conflict between the terms in this Option Agreement and the Plan, the terms of the Plan will control. Capitalized terms not explicitly defined in this Option Agreement or in the Grant Notice but defined in the Plan will have the same definitions as in the Plan.

The details of your option, in addition to those set forth in the Grant Notice and the Plan, are as follows:

**1. VESTING.** Subject to the provisions contained herein, your option will vest as provided in your Grant Notice. Vesting will cease upon the termination of your Continuous Service.

**2. NUMBER OF SHARES AND EXERCISE PRICE.** The number of shares of Common Stock subject to your option and your exercise price per share in your Grant Notice will be adjusted for Capitalization Adjustments.

**3. EXERCISE RESTRICTION FOR NON-EXEMPT EMPLOYEES.** If you are an Employee eligible for overtime compensation under the Fair Labor Standards Act of 1938, as amended (that is, a “*Non-Exempt Employee*”), and except as otherwise provided in the Plan, you may not exercise your option until you have completed at least six (6) months of Continuous Service measured from the Date of Grant, even if you have already been an employee for more than six (6) months. Consistent with the provisions of the Worker Economic Opportunity Act, you may exercise your option as to any vested portion prior to such six (6) month anniversary in the case of (i) your death or disability, (ii) a Corporate Transaction in which your option is not assumed, continued or substituted, (iii) a Change in Control or (iv) your termination of Continuous Service on your “retirement” (as defined in the Company’s benefit plans).

**4. METHOD OF PAYMENT.** You must pay the full amount of the exercise price for the shares you wish to exercise. You may pay the exercise price in cash or by check, bank draft or money order payable to the Company or in any other manner permitted by your Grant Notice, which may include one or more of the following:

**(a)** Pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board that, prior to the issuance of Common Stock, results in either the receipt of cash (or check) by the Company or the receipt of irrevocable instructions to pay the aggregate exercise price to the Company from the sales proceeds. This manner of payment is also known as a “broker-assisted exercise”, “same day sale”, or “sell to cover”.

**(b)** By delivery to the Company (either by actual delivery or attestation) of already-owned shares of Common Stock that are owned free and clear of any liens, claims, encumbrances or security interests, and that are valued at Fair Market Value on the date of exercise. “Delivery” for these purposes, in the sole discretion of the Company at the time you exercise your option, will include delivery to the

Company of your attestation of ownership of such shares of Common Stock in a form approved by the Company. You may not exercise your option by delivery to the Company of Common Stock if doing so would violate the provisions of any law, regulation or agreement restricting the redemption of the Company's stock.

(c) If this option is a Nonstatutory Stock Option, subject to the consent of the Company at the time of exercise, by a "net exercise" arrangement pursuant to which the Company will reduce the number of shares of Common Stock issued upon exercise of your option by the largest whole number of shares with a Fair Market Value that does not exceed the aggregate exercise price. You must pay any remaining balance of the aggregate exercise price not satisfied by the "net exercise" in cash or other permitted form of payment. Shares of Common Stock will no longer be outstanding under your option and will not be exercisable thereafter if those shares (i) are used to pay the exercise price pursuant to the "net exercise," (ii) are delivered to you as a result of such exercise, and (iii) are withheld to satisfy your tax withholding obligations.

5. **WHOLE SHARES.** You may exercise your option only for whole shares of Common Stock.

6. **SECURITIES LAW COMPLIANCE.** In no event may you exercise your option unless the shares of Common Stock issuable upon exercise are then registered under the Securities Act or, if not registered, the Company has determined that your exercise and the issuance of the shares would be exempt from the registration requirements of the Securities Act. The exercise of your option also must comply with all other applicable laws and regulations governing your option, and you may not exercise your option if the Company determines that such exercise would not be in material compliance with such laws and regulations (including any restrictions on exercise required for compliance with Treas. Reg. 1.401(k)-1(d)(3), if applicable).

7. **TERM.** You may not exercise your option before the Date of Grant or after the expiration of the option's term. The term of your option expires, subject to the provisions of Section 5(h) of the Plan and the Grant Notice, upon the earliest of the following:

(a) immediately upon the date on which the event giving rise to your termination of Continuous Service for Cause occurs (or, if required by law, the date of termination of Continuous Service for Cause);

(b) three (3) months after the termination of your Continuous Service for any reason other than Cause, your Disability or your death (except as otherwise provided in Section 7(d) below); *provided, however*, that if during any part of such three (3) month period your option is not exercisable solely because of the condition set forth in the section above relating to "Securities Law Compliance," your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service; *provided further*, if during any part of such three (3) month period, the sale of any Common Stock received upon exercise of your option would violate the Company's insider trading policy, then your option will not expire until the earlier of the Expiration Date or until it has been exercisable for an aggregate period of three (3) months after the termination of your Continuous Service during which the sale of the Common Stock received upon exercise of your option would not be in violation of the Company's insider trading policy. Notwithstanding the foregoing, if (i) you are a Non-Exempt Employee, (ii) your Continuous Service terminates within six (6) months after the Date of Grant, and (iii) you have vested in a portion of your option at the time of your termination of Continuous Service, your option will not expire until the earlier of (x) the later of (A) the date that is seven (7) months after the Date of Grant, and (B) the date that is three (3) months after the termination of your Continuous Service, and (y) the Expiration Date;

(c) twelve (12) months after the termination of your Continuous Service due to your Disability (except as otherwise provided in Section 7(d)) below;

(d) eighteen (18) months after your death if you die either during your Continuous Service or within three (3) months after your Continuous Service terminates for any reason other than Cause;

(e) in certain circumstances upon the effective date of a Transaction as set forth in the Plan;

(f) the Expiration Date indicated in your Grant Notice; or

(g) the day before the tenth (10th) anniversary of the Date of Grant.

If your option is an Incentive Stock Option, note that to obtain the federal income tax advantages associated with an Incentive Stock Option, the Code requires that at all times beginning on the Date of Grant and ending on the day three (3) months before the date of your option's exercise, you must be an employee of the Company or an Affiliate, except in the event of your death or Disability. The Company has provided for extended exercisability of your option under certain circumstances for your benefit but cannot guarantee that your option will necessarily be treated as an Incentive Stock Option if you continue to provide services to the Company or an Affiliate as a Consultant or Director after your employment terminates or if you otherwise exercise your option more than three (3) months after the date your employment with the Company or an Affiliate terminates.

## **8. EXERCISE.**

(a) You may exercise the vested portion of your option during its term by (i) delivering a Notice of Exercise (in a form designated by the Company) or completing such other documents and/or procedures designated by the Company for exercise and (ii) paying the exercise price and any applicable withholding taxes to the Company's Secretary, stock plan administrator, or such other person as the Company may designate, together with such additional documents as the Company may then require.

(b) By exercising your option you agree that, as a condition to any exercise of your option, the Company may require you to enter into an arrangement providing for the payment by you to the Company of any tax withholding obligation of the Company arising by reason of (i) the exercise of your option, (ii) the lapse of any substantial risk of forfeiture to which the shares of Common Stock are subject at the time of exercise, or (iii) the disposition of shares of Common Stock acquired upon such exercise.

(c) If your option is an Incentive Stock Option, by exercising your option you agree that you will notify the Company in writing within fifteen (15) days after the date of any disposition of any of the shares of the Common Stock issued upon exercise of your option that occurs within two (2) years after the Date of Grant or within one (1) year after such shares of Common Stock are transferred upon exercise of your option.

**9. TRANSFERABILITY.** Except as otherwise provided in this Section 9, your option is not transferable, except by will or by the laws of descent and distribution, and is exercisable during your life only by you.

(a) **Certain Trusts.** Upon receiving written permission from the Board or its duly authorized designee, you may transfer your option to a trust if you are considered to be the sole beneficial

owner (determined under Section 671 of the Code and applicable state law) while the option is held in the trust. You and the trustee must enter into transfer and other agreements required by the Company.

**(b) Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your option pursuant to the terms of a domestic relations order, official marital settlement agreement or other divorce or separation instrument as permitted by Treasury Regulation 1.421-1(b)(2) that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this option with the Company prior to finalizing the domestic relations order or marital settlement agreement to help ensure the required information is contained within the domestic relations order or marital settlement agreement. If this option is an Incentive Stock Option, this option may be deemed to be a Nonstatutory Stock Option as a result of such transfer.

**(c) Beneficiary Designation.** Upon receiving written permission from the Board or its duly authorized designee, you may, by delivering written notice to the Company, in a form approved by the Company and any broker designated by the Company to handle option exercises, designate a third party who, on your death, will thereafter be entitled to exercise this option and receive the Common Stock or other consideration resulting from such exercise. In the absence of such a designation, your executor or administrator of your estate will be entitled to exercise this option and receive, on behalf of your estate, the Common Stock or other consideration resulting from such exercise.

**10. OPTION NOT A SERVICE CONTRACT.** Your option is not an employment or service contract, and nothing in your option will be deemed to create in any way whatsoever any obligation on your part to continue in the employ of the Company or an Affiliate, or of the Company or an Affiliate to continue your employment. In addition, nothing in your option will obligate the Company or an Affiliate, their respective stockholders, boards of directors, officers or employees to continue any relationship that you might have as a Director or Consultant for the Company or an Affiliate.

#### **11. WITHHOLDING OBLIGATIONS.**

**(a)** At the time you exercise your option, in whole or in part, and at any time thereafter as requested by the Company, you hereby authorize withholding from payroll and any other amounts payable to you, and otherwise agree to make adequate provision for (including by means of a "same day sale" pursuant to a program developed under Regulation T as promulgated by the Federal Reserve Board to the extent permitted by the Company), any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or an Affiliate, if any, which arise in connection with the exercise of your option.

**(b)** If this option is a Nonstatutory Stock Option, then upon your request and subject to approval by the Company, and compliance with any applicable legal conditions or restrictions, the Company may withhold from fully vested shares of Common Stock otherwise issuable to you upon the exercise of your option a number of whole shares of Common Stock having a Fair Market Value, determined by the Company as of the date of exercise, not in excess of the minimum amount of tax required to be withheld by law (or such lower amount as may be necessary to avoid classification of your option as a liability for financial accounting purposes). If the date of determination of any tax withholding obligation is deferred to a date later than the date of exercise of your option, share withholding pursuant to the preceding sentence shall not be permitted unless you make a proper and timely election under Section 83(b) of the Code, covering the aggregate number of shares of Common Stock acquired upon such exercise with respect to which such determination is otherwise deferred, to accelerate the determination of such tax withholding obligation to the date of exercise of your option. Notwithstanding the filing of such election,

shares of Common Stock shall be withheld solely from fully vested shares of Common Stock determined as of the date of exercise of your option that are otherwise issuable to you upon such exercise. Any adverse consequences to you arising in connection with such share withholding procedure shall be your sole responsibility.

(c) You may not exercise your option unless the tax withholding obligations of the Company and/or any Affiliate are satisfied. Accordingly, you may not be able to exercise your option when desired even though your option is vested, and the Company will have no obligation to issue a certificate for such shares of Common Stock or release such shares of Common Stock from any escrow provided for herein, if applicable, unless such obligations are satisfied.

**12. TAX CONSEQUENCES.** You hereby agree that the Company does not have a duty to design or administer the Plan or its other compensation programs in a manner that minimizes your tax liabilities. You will not make any claim against the Company, or any of its Officers, Directors, Employees or Affiliates related to tax liabilities arising from your option or your other compensation. In particular, you acknowledge that this option is exempt from Section 409A of the Code only if the exercise price per share specified in the Grant Notice is at least equal to the “fair market value” per share of the Common Stock on the Date of Grant and there is no other impermissible deferral of compensation associated with the option.

**13. NOTICES.** Any notices provided for in your option or the Plan will be given in writing (including electronically) and will be deemed effectively given upon receipt or, in the case of notices delivered by mail by the Company to you, five (5) days after deposit in the United States mail, postage prepaid, addressed to you at the last address you provided to the Company. The Company may, in its sole discretion, decide to deliver any documents related to participation in the Plan and this option by electronic means or to request your consent to participate in the Plan by electronic means. By accepting this option, you consent to receive such documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**14. GOVERNING PLAN DOCUMENT.** Your option is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your option, and is further subject to all interpretations, amendments, rules and regulations, which may from time to time be promulgated and adopted pursuant to the Plan. If there is any conflict between the provisions of your option and those of the Plan, the provisions of the Plan will control. In addition, your option (and any compensation paid or shares issued under your option) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law.

**15. OTHER DOCUMENTS.** You hereby acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company’s policy permitting certain individuals to sell shares only during certain “window” periods and the Company’s insider trading policy, in effect from time to time.

**16. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS.** The value of this option will not be included as compensation, earnings, salaries, or other similar terms used when calculating your benefits under any employee benefit plan sponsored by the Company or any Affiliate, except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any of the Company’s or any Affiliate’s employee benefit plans.

**17. VOTING RIGHTS.** You will not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this option until such shares are issued to you. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this option, and no action taken pursuant to its provisions, will create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

**18. SEVERABILITY.** If all or any part of this Option Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity will not invalidate any portion of this Option Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Option Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

**19. MISCELLANEOUS.**

**(a)** The rights and obligations of the Company under your option will be transferable to any one or more persons or entities, and all covenants and agreements hereunder will inure to the benefit of, and be enforceable by the Company's successors and assigns.

**(b)** You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your option.

**(c)** You acknowledge and agree that you have reviewed your option in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your option, and fully understand all provisions of your option.

**(d)** This Option Agreement will be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

**(e)** All obligations of the Company under the Plan and this Option Agreement will be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

\* \* \*

This Option Agreement will be deemed to be signed by you upon the signing by you of the Grant Notice to which it is attached.

**ATTACHMENT II**

**2015 EQUITY INCENTIVE PLAN**

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**ATTACHMENT III**  
**NOTICE OF EXERCISE**

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**NOTICE OF EXERCISE**

Aclaris Therapeutics, Inc.  
Attention: Stock Plan Administrator  
640 Lee Road, Suite 200  
Wayne, PA 19087

Date of Exercise: \_\_\_\_\_

This constitutes notice to Aclaris Therapeutics, Inc. (the "**Company**") under my stock option that I elect to purchase the below number of shares of Common Stock of the Company (the "**Shares**") for the price set forth below.

Type of option (check one):	Incentive <input type="checkbox"/>	Nonstatutory <input type="checkbox"/>
Stock option dated:	_____	_____
Number of Shares as to which option is exercised:	_____	_____
Certificates to be issued in name of:	_____	_____
Total exercise price:	\$ _____	\$ _____
Cash payment delivered herewith:	\$ _____	\$ _____
Value of _____ Shares delivered herewith:	\$ _____	\$ _____
Regulation T Program (cashless exercise):	\$ _____	\$ _____

By this exercise, I agree (i) to provide such additional documents as you may require pursuant to the terms of the Aclaris Therapeutics, Inc. 2015 Equity Incentive Plan, (ii) to provide for the payment by me to you (in the manner designated by you) of your withholding obligation, if any, relating to the exercise of this option, and (iii) if this exercise relates to an Incentive Stock Option, to notify you in writing within fifteen (15) days after the date of any disposition of any of the Shares issued upon exercise of this option that occurs within two (2) years after the date of grant of this option or within one (1) year after such Shares are issued upon exercise of this option.

Very truly yours,

\_\_\_\_\_  
Signature

\_\_\_\_\_  
Print Name



**ACLARIS THERAPEUTICS, INC.**  
**RESTRICTED STOCK UNIT GRANT NOTICE**  
**(2015 EQUITY INCENTIVE PLAN)**

Aclaris Therapeutics, Inc. (the “**Company**”), pursuant to Section 6(b) of the Company’s 2015 Equity Incentive Plan (the “**Plan**”), hereby awards to Participant a Restricted Stock Unit Award for the number of shares of the Company’s Common Stock (“**Restricted Stock Units**”) set forth below (the “**Award**”). The Award is subject to all of the terms and conditions as set forth in this notice of grant (this “**Restricted Stock Unit Grant Notice**”) and in the Plan and the Restricted Stock Unit Award Agreement (the “**Award Agreement**”), both of which are attached hereto and incorporated herein in their entirety. Capitalized terms not otherwise defined herein shall have the meanings set forth in the Plan or the Award Agreement. In the event of any conflict between the terms in the Award and the Plan, the terms of the Plan shall control.

Participant: \_\_\_\_\_  
Date of Grant: \_\_\_\_\_  
Number of Restricted Stock Units/Shares: \_\_\_\_\_

**Vesting Schedule:** The shares subject to the Award shall vest as follows: [\_\_\_\_\_], subject to Participant’s Continuous Service through each such date.

**Termination:** Notwithstanding anything to the contrary in this Restricted Stock Unit Grant Notice or the Award Agreement, if the [INSERT PERFORMANCE CONDITION] is not achieved by [DATE], then the unvested Restricted Stock Units subject to this Award shall not vest, the Award will terminate on [DATE] and Participant shall have no further right, title or interest in this Award or the shares of Common Stock subject to this Award.

**Issuance Schedule:** Subject to any change on a Capitalization Adjustment, one share of Common Stock will be issued for each Restricted Stock Unit that vests at the time set forth in Section 6 of the Award Agreement.

**Additional Terms/Acknowledgements:** Participant acknowledges receipt of, and understands and agrees to, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan. Participant further acknowledges that as of the Date of Grant, this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan set forth the entire understanding between Participant and the Company regarding the acquisition of the Common Stock pursuant to the Award specified above and supersede all prior oral and written agreements on the terms of this Award with the exception, if applicable, of (i) any compensation recovery policy that is adopted by the Company or is otherwise required by applicable law, and (ii) any written employment or severance arrangement that would provide for vesting acceleration of this Award upon the terms and conditions set forth therein.

By accepting this Award, Participant acknowledges having received and read this Restricted Stock Unit Grant Notice, the Award Agreement and the Plan and agrees to all of the terms and conditions set forth in

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these documents. Participant consents to receive Plan documents by electronic delivery and to participate in the Plan through an on-line or electronic system established and maintained by the Company or another third party designated by the Company.

**ACLARIS THERAPEUTICS, INC.**

**PARTICIPANT**

By: \_\_\_\_\_  
Signature

\_\_\_\_\_  
Signature

Title: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

**ATTACHMENTS:** Restricted Stock Unit Award Agreement and 2015 Equity Incentive Plan

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**ATTACHMENT I**

**RESTRICTED STOCK UNIT AWARD AGREEMENT**

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**ACLARIS THERAPEUTICS, INC.**  
**RESTRICTED STOCK UNIT AWARD AGREEMENT**  
**(2015 EQUITY INCENTIVE PLAN)**

Pursuant to the Restricted Stock Unit Grant Notice (the “*Grant Notice*”) and this Restricted Stock Unit Award Agreement (the “*Agreement*”), Aclaris Therapeutics, Inc. (the “*Company*”) has awarded you (“*Participant*”) a Restricted Stock Unit Award (the “*Award*”) pursuant to Section 6(b) of the Company’s 2015 Equity Incentive Plan (the “*Plan*”) for the number of Restricted Stock Units/shares indicated in the Grant Notice. Capitalized terms not explicitly defined in this Agreement or the Grant Notice shall have the same meanings given to them in the Plan. The terms of your Award, in addition to those set forth in the Grant Notice, are as follows.

**1. GRANT OF THE AWARD.** This Award represents the right to be issued on a future date one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 below) as indicated in the Grant Notice. As of the Date of Grant, the Company will credit to a bookkeeping account maintained by the Company for your benefit (the “*Account*”) the number of Restricted Stock Units/shares of Common Stock subject to the Award. This Award was granted in consideration of your services to the Company.

**2. VESTING.** Subject to the limitations contained herein and in the Grant Notice, your Award will vest, if at all, in accordance with the vesting schedule provided in the Grant Notice, provided that vesting will cease upon the termination of your Continuous Service. Upon such termination of your Continuous Service, the Restricted Stock Units/shares of Common Stock credited to the Account that were not vested on the date of such termination will be forfeited at no cost to the Company and you will have no further right, title or interest in or to such underlying shares of Common Stock.

**3. NUMBER OF SHARES.** The number of Restricted Stock Units/shares subject to your Award may be adjusted from time to time for Capitalization Adjustments, as provided in the Plan. Any additional Restricted Stock Units, shares, cash or other property that becomes subject to the Award pursuant to this Section 3, if any, shall be subject, in a manner determined by the Board, to the same forfeiture restrictions, restrictions on transferability, and time and manner of delivery as applicable to the other Restricted Stock Units and shares covered by your Award. Notwithstanding the provisions of this Section 3, no fractional shares or rights for fractional shares of Common Stock shall be created pursuant to this Section 3. Any fraction of a share will be rounded down to the nearest whole share.

**4. SECURITIES LAW COMPLIANCE.** You may not be issued any Common Stock under your Award unless the shares of Common Stock underlying the Restricted Stock Units are either (i) then registered under the Securities Act, or (ii) the Company has determined that such issuance would be exempt from the registration requirements of the Securities Act. Your Award must also comply with other applicable laws and regulations governing the Award, and you shall not receive such Common Stock if the Company determines that such receipt would not be in material compliance with such laws and regulations.

5. **TRANSFER RESTRICTIONS.** Prior to the time that shares of Common Stock have been delivered to you, you may not transfer, pledge, sell or otherwise dispose of this Award or the shares issuable in respect of your Award, except as expressly provided in this Section 5. For example, you may not use shares that may be issued in respect of your Restricted Stock Units as security for a loan. The restrictions on transfer set forth herein will lapse upon delivery to you of shares in respect of your vested Restricted Stock Units.

(a) **Death.** Your Award is transferable by will and by the laws of descent and distribution. At your death, vesting of your Award will cease and your executor or administrator of your estate shall be entitled to receive, on behalf of your estate, any Common Stock or other consideration that vested but was not issued before your death.

(b) **Domestic Relations Orders.** Upon receiving written permission from the Board or its duly authorized designee, and provided that you and the designated transferee enter into transfer and other agreements required by the Company, you may transfer your right to receive the distribution of Common Stock or other consideration hereunder, pursuant to a domestic relations order or marital settlement agreement that contains the information required by the Company to effectuate the transfer. You are encouraged to discuss the proposed terms of any division of this Award with the Company's Chief Legal Officer prior to finalizing the domestic relations order or marital settlement agreement to verify that you may make such transfer, and if so, to help ensure the required information is contained within the domestic relations order or marital settlement agreement.

## 6. **DATE OF ISSUANCE.**

(a) The issuance of shares in respect of the Restricted Stock Units is intended to comply with Treasury Regulations Section 1.409A-1(b)(4) and will be construed and administered in such a manner. Subject to the satisfaction of the withholding obligations set forth in this Agreement, in the event one or more Restricted Stock Units vests, the Company shall issue to you one (1) share of Common Stock for each Restricted Stock Unit that vests on the applicable vesting date(s) (subject to any adjustment under Section 3 above). The issuance date determined by this paragraph is referred to as the "**Original Issuance Date**".

(b) If the Original Issuance Date falls on a date that is not a business day, delivery shall instead occur on the next following business day. In addition, if:

(i) the Original Issuance Date does not occur (1) during an "open window period" applicable to you, as determined by the Company in accordance with the Company's then-effective policy on trading in Company securities, or (2) on a date when you are otherwise permitted to sell shares of Common Stock on an established stock exchange or stock market, *and*

(ii) either (1) Withholding Taxes do not apply, or (2) the Company decides, prior to the Original Issuance Date, (A) not to satisfy the Withholding Taxes by withholding shares of Common Stock from the shares otherwise due, on the Original Issuance Date, to you under this Award, and (B) not to permit you to pay your Withholding Taxes in cash,

then the shares that would otherwise be issued to you on the Original Issuance Date will not be delivered on such Original Issuance Date and will instead be delivered on the first business day when you are not prohibited from selling shares of the Company's Common Stock in the open public market, but in no event later than December 31 of the calendar year in which the Original Issuance Date occurs (that is, the last day of your taxable year in which the Original Issuance Date occurs), or, if and only if permitted in a manner that complies with Treasury Regulations Section 1.409A-1(b)(4), no later than the date that is the 15th day of the third calendar month of the applicable year following the year in which the shares of Common Stock under this Award are no longer subject to a "substantial risk of forfeiture" within the meaning of Treasury Regulations Section 1.409A-1(d).

(c) The form of delivery (*e.g.*, a stock certificate or electronic entry evidencing such shares) shall be determined by the Company.

7. **DIVIDENDS.** You shall receive no benefit or adjustment to your Award with respect to any cash dividend, stock dividend or other distribution that does not result from a Capitalization Adjustment.

8. **RESTRICTIVE LEGENDS.** The shares of Common Stock issued under your Award shall be endorsed with appropriate legends as determined by the Company.

9. **EXECUTION OF DOCUMENTS.** You hereby acknowledge and agree that the manner selected by the Company by which you indicate your consent to your Grant Notice is also deemed to be your execution of your Grant Notice and of this Agreement. You further agree that such manner of indicating consent may be relied upon as your signature for establishing your execution of any documents to be executed in the future in connection with your Award.

**10. AWARD NOT A SERVICE CONTRACT.**

(a) Nothing in this Agreement (including, but not limited to, the vesting of your Award or the issuance of the shares subject to your Award), the Plan or any covenant of good faith and fair dealing that may be found implicit in this Agreement or the Plan shall: (i) confer upon you any right to continue in the employ of, or affiliation with, the Company or an Affiliate; (ii) constitute any promise or commitment by the Company or an Affiliate regarding the fact or nature of future positions, future work assignments, future compensation or any other term or condition of employment or affiliation; (iii) confer any right or benefit under this Agreement or the Plan unless such right or benefit has specifically accrued under the terms of this Agreement or Plan; or (iv) deprive the Company of the right to terminate you at will and without regard to any future vesting opportunity that you may have.

(b) The Company has the right to reorganize, sell, spin-out or otherwise restructure one or more of its businesses or Affiliates at any time or from time to time, as it deems appropriate (a "**reorganization**"). Such a reorganization could result in the termination of your Continuous Service, or the termination of Affiliate status of your employer and the loss of benefits available to you under this Agreement, including but not limited to, the termination of the right to continue vesting in the Award. This Agreement, the Plan, the transactions contemplated hereunder and the vesting schedule set forth herein or any covenant of good faith and fair dealing

that may be found implicit in any of them do not constitute an express or implied promise of continued engagement as an employee or consultant for the term of this Agreement, for any period, or at all, and shall not interfere in any way with the Company's right to conduct a reorganization.

## 11. WITHHOLDING OBLIGATIONS.

(a) On each vesting date, and on or before the time you receive a distribution of the shares underlying your Restricted Stock Units, and at any other time as reasonably requested by the Company in accordance with applicable tax laws, you hereby authorize any required withholding from the Common Stock issuable to you and/or otherwise agree to make adequate provision in cash for any sums required to satisfy the federal, state, local and foreign tax withholding obligations of the Company or any Affiliate that arise in connection with your Award (the "**Withholding Taxes**"). Additionally, the Company or any Affiliate may, in its sole discretion, satisfy all or any portion of the Withholding Taxes obligation relating to your Award by any of the following means or by a combination of such means: (i) withholding from any compensation otherwise payable to you by the Company; (ii) causing you to tender a cash payment; (iii) permitting or requiring you to enter into a "same day sale" commitment, if applicable, with a broker-dealer that is a member of the Financial Industry Regulatory Authority (a "**FINRA Dealer**") whereby you irrevocably elect to sell a portion of the shares to be delivered in connection with your Restricted Stock Units to satisfy the Withholding Taxes and whereby the FINRA Dealer irrevocably commits to forward the proceeds necessary to satisfy the Withholding Taxes directly to the Company and/or its Affiliates; or (iv) withholding shares of Common Stock from the shares of Common Stock issued or otherwise issuable to you in connection with the Award with a Fair Market Value (measured as of the date shares of Common Stock are issued to pursuant to Section 6) equal to the amount of such Withholding Taxes; *provided, however*, that the number of such shares of Common Stock so withheld will not exceed the amount necessary to satisfy the Company's required tax withholding obligations using the minimum statutory withholding rates for federal, state, local and foreign tax purposes, including payroll taxes, that are applicable to supplemental taxable income; and *provided, further*, that to the extent necessary to qualify for an exemption from application of Section 16(b) of the Exchange Act, if applicable, such share withholding procedure will be subject to the express prior approval of the Company's Compensation Committee.

(b) Unless the tax withholding obligations of the Company and/or any Affiliate are satisfied, the Company shall have no obligation to deliver to you any Common Stock.

(c) In the event the Company's obligation to withhold arises prior to the delivery to you of Common Stock or it is determined after the delivery of Common Stock to you that the amount of the Company's withholding obligation was greater than the amount withheld by the Company, you agree to indemnify and hold the Company harmless from any failure by the Company to withhold the proper amount.

12. **TAX CONSEQUENCES.** The Company has no duty or obligation to minimize the tax consequences to you of this Award and shall not be liable to you for any adverse tax consequences to you arising in connection with this Award. You are hereby advised to consult with your own personal tax, financial and/or legal advisors regarding the tax consequences of this Award and by

signing the Grant Notice, you have agreed that you have done so or knowingly and voluntarily declined to do so. You understand that you (and not the Company) shall be responsible for your own tax liability that may arise as a result of this investment or the transactions contemplated by this Agreement.

**13. UNSECURED OBLIGATION.** Your Award is unfunded, and as a holder of a vested Award, you shall be considered an unsecured creditor of the Company with respect to the Company's obligation, if any, to issue shares or other property pursuant to this Agreement. You shall not have voting or any other rights as a stockholder of the Company with respect to the shares to be issued pursuant to this Agreement until such shares are issued to you pursuant to Section 6 of this Agreement. Upon such issuance, you will obtain full voting and other rights as a stockholder of the Company. Nothing contained in this Agreement, and no action taken pursuant to its provisions, shall create or be construed to create a trust of any kind or a fiduciary relationship between you and the Company or any other person.

**14. NOTICES.** Any notice or request required or permitted hereunder shall be given in writing to each of the other parties hereto and shall be deemed effectively given on the earlier of (i) the date of personal delivery, including delivery by express courier, or delivery via electronic means, or (ii) the date that is five (5) days after deposit in the United States Post Office (whether or not actually received by the addressee), by registered or certified mail with postage and fees prepaid, addressed at the following addresses, or at such other address(es) as a party may designate by ten (10) days' advance written notice to each of the other parties hereto:

<b>COMPANY:</b>	Aclaris Therapeutics, Inc. Attn: Stock Administrator 640 Lee Road, Suite 200 Wayne, PA 19087
<b>PARTICIPANT:</b>	Your address as on file with the Company at the time notice is given

**15. HEADINGS.** The headings of the Sections in this Agreement are inserted for convenience only and shall not be deemed to constitute a part of this Agreement or to affect the meaning of this Agreement.

**16. MISCELLANEOUS.**

**(a)** The rights and obligations of the Company under your Award shall be transferable by the Company to any one or more persons or entities, and all covenants and agreements hereunder shall inure to the benefit of, and be enforceable by, the Company's successors and assigns.

**(b)** You agree upon request to execute any further documents or instruments necessary or desirable in the sole determination of the Company to carry out the purposes or intent of your Award.

(c) You agree that you will not sell, dispose of, transfer, make any short sale of, grant any option for the purchase of, or enter into any hedging or similar transaction with the same economic effect as a sale with respect to any shares of Common Stock or other securities of the Company held by you, for a period of 180 days following the effective date of a registration statement of the Company filed under the Securities Act or such longer period as the underwriters or the Company will request to facilitate compliance with FINRA Rule 2711 or NYSE Member Rule 472 or any successor or similar rules or regulation (the “**Lock-Up Period**”). You further agree to execute and deliver such other agreements as may be reasonably requested by the Company or the underwriters that are consistent with the foregoing or that are necessary to give further effect thereto. In order to enforce the foregoing covenant, the Company may impose stop-transfer instructions with respect to your shares of Common Stock until the end of such period. You also agree that any transferee of any shares of Common Stock (or other securities) of the Company held by you will be bound by this Section 16(c). The underwriters of the Company’s stock are intended third party beneficiaries of this Section 16(c) and will have the right, power and authority to enforce the provisions hereof as though they were a party hereto.

(d) You acknowledge and agree that you have reviewed your Award in its entirety, have had an opportunity to obtain the advice of counsel prior to executing and accepting your Award and fully understand all provisions of your Award.

(e) This Agreement shall be subject to all applicable laws, rules, and regulations, and to such approvals by any governmental agencies or national securities exchanges as may be required.

(f) All obligations of the Company under the Plan and this Agreement shall be binding on any successor to the Company, whether the existence of such successor is the result of a direct or indirect purchase, merger, consolidation, or otherwise, of all or substantially all of the business and/or assets of the Company.

**17. GOVERNING PLAN DOCUMENT.** Your Award is subject to all the provisions of the Plan, the provisions of which are hereby made a part of your Award, and is further subject to all interpretations, amendments, rules and regulations which may from time to time be promulgated and adopted pursuant to the Plan. Your Award (and any compensation paid or shares issued under your Award) is subject to recoupment in accordance with The Dodd–Frank Wall Street Reform and Consumer Protection Act and any implementing regulations thereunder, any clawback policy adopted by the Company and any compensation recovery policy otherwise required by applicable law. No recovery of compensation under such a clawback policy will be an event giving rise to a right to voluntarily terminate employment upon a resignation for “good reason,” or for a “constructive termination” or any similar term under any plan of or agreement with the Company.

**18. EFFECT ON OTHER EMPLOYEE BENEFIT PLANS.** The value of the Award subject to this Agreement shall not be included as compensation, earnings, salaries, or other similar terms used when calculating benefits under any employee benefit plan (other than the Plan) sponsored by the Company or any Affiliate except as such plan otherwise expressly provides. The Company expressly reserves its rights to amend, modify, or terminate any or all of the employee benefit plans of the Company or any Affiliate.

**19. CHOICE OF LAW.** The interpretation, performance and enforcement of this Agreement shall be governed by the law of the State of Delaware without regard to that state's conflicts of laws rules.

**20. SEVERABILITY.** If all or any part of this Agreement or the Plan is declared by any court or governmental authority to be unlawful or invalid, such unlawfulness or invalidity shall not invalidate any portion of this Agreement or the Plan not declared to be unlawful or invalid. Any Section of this Agreement (or part of such a Section) so declared to be unlawful or invalid shall, if possible, be construed in a manner which will give effect to the terms of such Section or part of a Section to the fullest extent possible while remaining lawful and valid.

**21. OTHER DOCUMENTS.** You acknowledge receipt of and the right to receive a document providing the information required by Rule 428(b)(1) promulgated under the Securities Act, which includes the Plan prospectus. In addition, you acknowledge receipt of the Company's Insider Trading Policy.

**22. AMENDMENT.** This Agreement may not be modified, amended or terminated except by an instrument in writing, signed by you and by a duly authorized representative of the Company. Notwithstanding the foregoing, this Agreement may be amended solely by the Board by a writing which specifically states that it is amending this Agreement, so long as a copy of such amendment is delivered to you, and provided that, except as otherwise expressly provided in the Plan, no such amendment materially adversely affecting your rights hereunder may be made without your written consent. Without limiting the foregoing, the Board reserves the right to change, by written notice to you, the provisions of this Agreement in any way it may deem necessary or advisable to carry out the purpose of the Award as a result of any change in applicable laws or regulations or any future law, regulation, ruling, or judicial decision, provided that any such change shall be applicable only to rights relating to that portion of the Award which is then subject to restrictions as provided herein.

**23. COMPLIANCE WITH SECTION 409A OF THE CODE.** This Award is intended to comply with the "short-term deferral" rule set forth in Treasury Regulation Section 1.409A-1(b)(4). Notwithstanding the foregoing, if it is determined that the Award fails to satisfy the requirements of the short-term deferral rule and is otherwise deferred compensation subject to Section 409A, and if you are a "Specified Employee" (within the meaning set forth in Section 409A(a)(2)(B)(i) of the Code) as of the date of your "separation from service" (within the meaning of Treasury Regulation Section 1.409A-1(h) and without regard to any alternative definition thereunder), then the issuance of any shares that would otherwise be made upon the date of the separation from service or within the first six (6) months thereafter will not be made on the originally scheduled date(s) and will instead be issued in a lump sum on the date that is six (6) months and one day after the date of the separation from service, with the balance of the shares issued thereafter in accordance with the original vesting and issuance schedule set forth above, but if and only if such delay in the issuance of the shares is necessary to avoid the imposition of adverse taxation on you in respect of the shares under Section 409A of the Code. Each installment of shares that vests is intended to constitute a "separate payment" for purposes of Treasury Regulation Section 1.409A-2(b)(2).

\* \* \* \* \*

This Restricted Stock Unit Award Agreement shall be deemed to be signed by the Company and the Participant upon the signing by the Participant of the Restricted Stock Unit Grant Notice to which it is attached.

2015 EQUITY INCENTIVE PLAN

## ACLARIS THERAPEUTICS, INC.

**AMENDED & RESTATED  
NON-EMPLOYEE DIRECTOR COMPENSATION POLICY**

Each member of the Board of Directors (the “**Board**”) who is not also serving as an employee of Aclaris Therapeutics, Inc. (the “**Company**”) or any of its affiliates or NeXeption, LLC or any affiliates of NeXeption, LLC (each such member, an “**Eligible Director**”) will receive the compensation described in this Amended & Restated Non-Employee Director Compensation Policy (this “**Policy**”) for his or her Board service effective as of the date of the Company’s 2019 annual meeting of stockholders (the date of the meeting being referred to as the “**Effective Date**”). An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash is to be paid or equity awards are to be granted, as the case may be. This Policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board. The terms and conditions of this Policy shall supersede any prior Non-Employee Director Compensation Policy of the Company.

### Annual Cash Compensation

The annual cash compensation amount set forth below is payable in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal year, with the pro-rated amount paid for the first fiscal quarter in which the Eligible Director provides the service, and regular full quarterly payments thereafter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
  - a. All Eligible Directors: \$40,000
2. Annual Committee Member Service Retainer:
  - a. Member of the Audit Committee: \$7,500
  - b. Member of the Compensation Committee: \$6,000
  - c. Member of the Nominating and Corporate Governance Committee: \$4,500
3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):
  - a. Chairman of the Audit Committee: \$12,500
  - b. Chairman of the Compensation Committee: \$8,000
  - c. Chairman of the Nominating and Corporate Governance Committee: \$4,500

### Equity Compensation

The equity compensation set forth below will be granted under the Company’s 2015 Equity Incentive Plan (the “**Plan**”). All stock options granted under this Policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the Company’s underlying common stock (the “**Common Stock**”) on the date of grant, and a term of ten years from the date of grant (subject to earlier termination in connection with a termination of service as provided in the Plan).

1. Initial Grant: On the date of the Eligible Director’s initial election to the Board, for each Eligible Director who is first elected to the Board following the Effective Date (or, if such date is not a market trading day, the first market trading day thereafter), the Eligible Director will be automatically, and without further action by the Board or Compensation Committee of the Board, granted a stock option to purchase 16,000 shares of the Company’s Common Stock, with an exercise price per share equal to 100% of the Fair Market Value of the Company’s Common Stock on the date of grant. The shares subject to each such stock option will vest in equal monthly
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installments for 36 months, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date[s].

2. Annual Grant: On the date of each annual stockholders meeting of the Company held on and after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholders meeting will be automatically, and without further action by the Board or Compensation Committee of the Board, granted (a) a stock option to purchase 11,000 shares of the Company's Common Stock, with an exercise price per share equal to 100% of the Fair Market Value of the Company's Common Stock on the date of grant or (b) if approved by the Board or the Compensation Committee of the Board prior to any such meeting, a number of restricted stock units at a ratio to the number of shares such Eligible Director would have received under clause (a) as determined by the Board or the Compensation Committee (or any combination of clause (a) and this clause (b)). The shares subject to each such stock option will vest in equal monthly installments for 12 months and the restricted stock units will vest in one installment on the first anniversary of the grant date, subject to the Eligible Director's Continuous Service through such vesting date[s].

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**FIRST AMENDMENT TO SUBLEASE**

This First Amendment to Sublease (this "Amendment") dated as of this 13th day of December, 2017 by and between **Aclaris Therapeutics, Inc.**, a Delaware corporation, with offices located at 101 Lindenwood Drive, Suite 400, Malvern, Pennsylvania 19355 ("Subtenant"), and **Auxilium Pharmaceuticals, LLC**, a Delaware limited liability company, with offices located at 1400 Atwater Drive, Malvern, PA 19355 ("Sublandlord").

**W I T N E S S E T H:**

**WHEREAS**, Sublandlord and Subtenant entered into that certain Sublease dated as of November 2, 2017 (the "Sublease"), pursuant to which Sublandlord subleased to Subtenant that certain Sublease Premises consisting of 33,019 square feet of space in the aggregate located at 640 Lee Road, Wayne, PA, comprised of the entire second floor of the Master Lease Premises and a portion of the first floor, as more fully described in the Lease;

**WHEREAS**, Sublandlord and Subtenant have agreed to modify the Sublease to permit Subtenant to make certain alterations to the Sublease Premises, subject to the terms and conditions hereof.

**NOW, THEREFORE**, for and in consideration of the aforesaid recitals and the covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged by the parties hereto, Sublandlord and Subtenant hereby agree as follows:

1. **Capitalized Terms.** Capitalized terms used herein, but not defined herein, shall have the meanings ascribed to such terms in the Sublease.

2. **Alterations to Sublease Premises.** Subtenant shall be permitted to make those certain alterations to the Subleased Premises as shown on and in accordance with the plans attached hereto as **Exhibit A**, provided that prior to the expiration of the Term, Subtenant, at its sole cost and expense, shall restore the Sublease Premises to its original condition that existed immediately prior to Subtenant's use of and alterations to the Sublease Premises. The Master Landlord has consented to such alterations to the Sublease Premises, subject to the restoration condition stated herein. Subtenant shall indemnify, defend and hold Sublandlord harmless from and against any and all losses, costs, damages, expenses and liability, including, but not limited to, reasonable attorneys' fees, which Sublandlord may incur in connection with Subtenant's alterations to and subsequent restoration of the Sublease Premises, including, without limitation, Subtenant's failure to restore the Sublease Premises to the satisfaction of Master Landlord before the expiration of the Term.

3. **Miscellaneous.** Except as hereinabove provided, all other terms and conditions of the Sublease shall remain unchanged and in full force and effect. This Amendment may be executed in counterparts, each of which shall be deemed an original, and all of which together shall constitute one Amendment. This Amendment together with the Sublease, is the complete understanding between the parties and supersedes all other prior agreements and representations concerning its subject matter.

*[Signatures on following page]*

**IN WITNESS WHEREOF**, this Amendment has been duly executed by Sublandlord and Subtenant as of the day and year first herein above written.

**SUBLANDLORD:**

AUXILIUM PHARMACEUTICALS, LLC  
a Delaware limited liability company

By: /s/ Lawrence A. Cunningham

\_\_\_\_\_  
Name: Lawrence A. Cunningham

Title: Executive Vice President, Human Resources

**SUBTENANT:**

ACLARIS THERAPEUTICS, INC.  
a Delaware corporation

By: /s/ Neal Walker

\_\_\_\_\_  
Name: Neal Walker

Title: President & CEO

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**EXHIBIT A**  
**ALTERATION PLANS**

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640 Lee Rd  
2nd Floor  
Chesterbrook, PA



## LOAN AND SECURITY AGREEMENT

**THIS LOAN AND SECURITY AGREEMENT** (as the same may from time to time be amended, modified, supplemented or restated, this “**Agreement**”) dated as of October 15, 2018 (the “**Effective Date**”) among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (“**Oxford**”), as collateral agent (in such capacity, “**Collateral Agent**”), the Lenders listed on Schedule 1.1 hereof or otherwise a party hereto from time to time including Oxford in its capacity as a Lender (each a “**Lender**” and collectively, the “**Lenders**”), and ACLARIS THERAPEUTICS, INC., a Delaware corporation (“**Parent**”) with offices located at 640 Lee Road, Suite 200, Wayne, PA 19087, Confluence Discovery Technologies, Inc., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 (“**CDT**”) and ACLARIS LIFE SCIENCES, INC., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 (“**ALS**”) (Parent, CDT and ALS, individually and collectively, jointly and severally, “**Borrower**”), provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders. The parties agree as follows:

### 1. ACCOUNTING AND OTHER TERMS

**1.1** Accounting terms not defined in this Agreement shall be construed in accordance with GAAP. Calculations and determinations must be made in accordance with GAAP. The term “financial statements” shall include the accompanying notes and schedules. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in Section 13. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. All references to “**Dollars**” or “**\$**” are United States Dollars, unless otherwise noted.

### 2. LOANS AND TERMS OF PAYMENT

**2.1 Promise to Pay.** Borrower hereby unconditionally promises to pay each Lender, the outstanding principal amount of all Term Loans advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

#### **2.2 Term Loans.**

(a) Availability.

(i) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, to make term loans to Borrower during the First Draw Period in an aggregate amount of Thirty Million Dollars (\$30,000,000.00) according to each Lender’s Term A Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “**Term A Loan**”, and collectively as the “**Term A Loans**”). After repayment, no Term A Loan may be re-borrowed.

(ii) Subject to the terms and conditions of this Agreement, the Lenders agree, severally and not jointly, during the Second Draw Period, to make term loans to Borrower in an aggregate amount up to Thirty Five Million Dollars (\$35,000,000.00) according to each Lender’s Term B Loan Commitment as set forth on Schedule 1.1 hereto (such term loans are hereinafter referred to singly as a “**Term B Loan**”, and collectively as the “**Term B Loans**”; each Term A Loan or Term B Loan is hereinafter referred to singly as a “**Term Loan**” and the Term A Loans and the Term B Loans are hereinafter referred to collectively as the “**Term Loans**”). After repayment, no Term B Loan may be re-borrowed.

(b) Repayment. Borrower shall make monthly payments of interest only commencing on the first (1<sup>st</sup>) Payment Date following the Funding Date of the Term Loan, and continuing on the Payment Date of each

successive month thereafter through and including the Payment Date immediately preceding the Amortization Date. Borrower agrees to pay, on the Funding Date of the Term Loan, any initial partial monthly interest payment otherwise due for the period between the Funding Date of the Term Loan and the first Payment Date thereof. Commencing on the Amortization Date, and continuing on the Payment Date of each month thereafter, Borrower shall make consecutive equal monthly payments of principal, together with applicable interest, in arrears, to each Lender, as calculated by Collateral Agent (which calculations shall be deemed correct absent manifest error) based upon: (1) the amount of such Lender's Term Loan, (2) the effective rate of interest, as determined in Section 2.3(a), and (3) a repayment schedule equal to twenty four (24) months. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on the Maturity Date. The Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d).

(c) Mandatory Prepayments. If the Term Loans are accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (ii) the Final Payment, (iii) the Prepayment Fee, plus (iv) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts. Notwithstanding (but without duplication with) the foregoing, on the Maturity Date, if the Final Payment had not previously been paid in full in connection with the prepayment of the Term Loans in full, Borrower shall pay to Collateral Agent, for payment to each Lender in accordance with its respective Pro Rata Share, the Final Payment in respect of the Term Loans.

(d) Permitted Prepayment of Term Loans.

(i) Borrower shall have the option to prepay all, but not less than all, of the Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, and (ii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon through the prepayment date, (B) the Final Payment, (C) the Prepayment Fee, plus (D) all other Obligations that are due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts.

(ii) Notwithstanding anything herein to the contrary, Borrower shall also have the option to prepay, once in any given three month period, part of Term Loans advanced by the Lenders under this Agreement, provided Borrower (i) provides written notice to Collateral Agent of its election to prepay the Term Loans at least ten (10) days prior to such prepayment, (ii) prepays such part of the Term Loans in an amount not less than Two Million Dollars (\$2,000,000.00), and (iii) pays to the Lenders on the date of such prepayment, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of (A) the portion of outstanding principal of such Term Loans plus all accrued and unpaid interest thereon through the prepayment date, (B) the applicable Final Payment, and (C) all other Obligations that are then due and payable, including Lenders' Expenses and interest at the Default Rate with respect to any past due amounts, and (D) the applicable Prepayment Fee with respect to the portion of such Term Loans being prepaid. For the purposes of clarity, any partial prepayment shall be applied pro-rata to all outstanding amounts under each Term Loan, and shall be applied pro-rata within each Term Loan tranche to reduce amortization payments under Section 2.2(b) on a pro-rata basis. For the avoidance of doubt, Borrower may make one or more partial prepayments prior to the Maturity Date.

### 2.3 Payment of Interest on the Credit Extensions.

(a) Interest Rate. Subject to Section 2.3(b), the principal amount outstanding under the Term Loans shall accrue interest at a floating per annum rate equal to the Basic Rate, determined by Collateral Agent from time to time, which interest shall be payable monthly in arrears in accordance with Sections 2.2(b) and 2.3(e). Interest shall accrue on each Term Loan commencing on, and including, the Funding Date of such Term Loan, and

shall accrue on the principal amount outstanding under such Term Loan through and including the day on which such Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a floating per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the “**Default Rate**”). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360-Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year, and the actual number of days elapsed.

(d) Debit of Accounts. Collateral Agent and each Lender may debit (or ACH) any deposit accounts, maintained by Borrower or any of its Subsidiaries, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes the Lenders under the Loan Documents when due. Any such debits (or ACH activity) shall not constitute a set-off.

(e) Payments. Except as otherwise expressly provided herein, all payments by Borrower under the Loan Documents shall be made to the respective Lender to which such payments are owed, at such Lender’s office in immediately available funds on the date specified herein. Unless otherwise provided, interest is payable monthly on the Payment Date of each month. Payments of principal and/or interest received after 2:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment is due the next Business Day and additional fees or interest, as applicable, shall continue to accrue until paid. All payments to be made by Borrower hereunder or under any other Loan Document, including payments of principal and interest, and all fees, expenses, indemnities and reimbursements, shall be made without set-off, recoupment or counterclaim, in lawful money of the United States and in immediately available funds.

**2.4 Secured Promissory Notes.** The Term Loans shall be evidenced by a Secured Promissory Note or Notes in the form attached as Exhibit D hereto (each a “**Secured Promissory Note**”), and shall be repayable as set forth in this Agreement. Borrower irrevocably authorizes each Lender to make or cause to be made, on or about the Funding Date of any Term Loan or at the time of receipt of any payment of principal on such Lender’s Secured Promissory Note, an appropriate notation on such Lender’s Secured Promissory Note Record reflecting the making of such Term Loan or (as the case may be) the receipt of such payment. The outstanding amount of each Term Loan set forth on such Lender’s Secured Promissory Note Record shall be prima facie evidence of the principal amount thereof owing and unpaid to such Lender, but the failure to record, or any error in so recording, any such amount on such Lender’s Secured Promissory Note Record shall not limit or otherwise affect the obligations of Borrower under any Secured Promissory Note or any other Loan Document to make payments of principal or interest on any Secured Promissory Note when due. Upon receipt of an affidavit of an officer of a Lender as to the loss, theft, destruction, or mutilation of its Secured Promissory Note, Borrower shall issue, in lieu thereof, a replacement Secured Promissory Note in the same principal amount thereof and of like tenor.

**2.5 Fees.** Borrower shall pay to Collateral Agent:

(a) Good Faith Deposit. An amount of Fifty Thousand Dollars (\$50,000.00) has been received by Collateral Agent as good faith deposit from Borrower on or about August 21, 2018, which amount shall be applied towards the Lender’s Expenses due on the Effective Date (it being agreed and understood that Borrower shall remain responsible for all Lender’s Expenses in accordance with Section 2.5(d) hereof) and the balance, if any, shall be applied towards other payment Obligations of Borrower hereunder in accordance with the Collateral Agent’s and Lenders’ discretion;

(b) Final Payment. The Final Payment, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(c) Prepayment Fee. The Prepayment Fee, when due hereunder, to be shared between the Lenders in accordance with their respective Pro Rata Shares;

(d) Lenders' Expenses. All Lenders' Expenses (including reasonable attorneys' fees and expenses for documentation and negotiation of this Agreement) incurred through and after the Effective Date, when due;

(e) Term A Loan Non-Utilization Fee. A full earned non-utilization fee equal to one percent (1.00%) of the amount of the Term A Loan not funded hereunder (i.e., the difference between Thirty Million Dollars (\$30,000,000.00) and the amount of Term A Loan funded hereunder), which shall be due and payable immediately upon the expiration or earlier termination of the First Draw Period or prepayment of the entire outstanding amount of the Term Loans pursuant to Section 2.2(d) of this Agreement, if upon such expiration, earlier termination or prepayment of the entire outstanding amount of the Term Loans pursuant to Section 2.2(d) of this Agreement the Borrower has not drawn the full amount of the Term A Loan in accordance with the provisions hereof; and

(f) Term B Loan Non-Utilization Fee. A full earned non-utilization fee equal to one percent (1.00%) of the amount of the Term B Loan not funded hereunder (i.e., the difference between Thirty Five Million Dollars (\$35,000,000.00) and the amount of Term B Loan funded hereunder), which shall be due and payable immediately upon the expiration or earlier termination of the Second Draw Period or prepayment of the entire outstanding amount of the Term Loans pursuant to Section 2.2(d) of this Agreement, if upon such expiration, earlier termination or prepayment of the entire outstanding amount of the Term Loans pursuant to Section 2.2(d) of this Agreement the Borrower has not drawn the full amount of the Term B Loan in accordance with the provisions hereof; provided, however, the non-utilization fee set forth in this Section 2.5(f) shall not become due and payable if the Second Draw Period does not commence.

**2.6 Withholding.** Payments received by the Lenders from Borrower hereunder will be made free and clear of and without deduction for any and all present or future taxes, levies, imposts, duties, deductions, withholdings, assessments, fees or other charges imposed by any governmental authority (including any interest, additions to tax or penalties applicable thereto). Specifically, however, if at any time any Governmental Authority, applicable law, regulation or international agreement requires Borrower to make any withholding or deduction from any such payment or other sum payable hereunder to the Lenders, Borrower hereby covenants and agrees that the amount due from Borrower with respect to such payment or other sum payable hereunder will be increased to the extent necessary to ensure that, after the making of such required withholding or deduction, each Lender receives a net sum equal to the sum which it would have received had no withholding or deduction been required and Borrower shall pay the full amount withheld or deducted to the relevant Governmental Authority. Borrower will, upon request, furnish the Lenders with proof reasonably satisfactory to the Lenders indicating that Borrower has made such withholding payment; provided, however, that Borrower need not make any withholding payment if the amount or validity of such withholding payment is contested in good faith by appropriate and timely proceedings and as to which payment in full is bonded or reserved against by Borrower. The agreements and obligations of Borrower contained in this Section 2.6 shall survive the termination of this Agreement.

### **3. CONDITIONS OF LOANS AND EFFECTIVENESS OF THIS AGREEMENT**

**3.1 Conditions Precedent to the Effectiveness of this Agreement.** This Agreement shall not be deemed to have become effective, unless on the Effective Date, Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

- (a) original Loan Agreement;
- (b) duly executed original Control Agreements with respect to any Collateral Accounts maintained by Borrower or any of its Subsidiaries that are required for Borrower's compliance with the provisions of Section 6.6 hereof;
- (c) the good standing certificates of Borrower and its Subsidiaries certified by the Secretary of State (or equivalent agency) of Borrower's and such Subsidiaries' jurisdiction of organization or formation and each jurisdiction in which Borrower and each Subsidiary is qualified to conduct business and Operating Documents, each as of a date no earlier than thirty (30) days prior to the Effective Date;
- (d) a completed Perfection Certificate for Borrower and each of its Subsidiaries;
- (e) the Annual Projections, for the current calendar year;
- (f) duly executed original officer's certificate for Borrower and each Subsidiary that is a party to the Loan Documents, in a form acceptable to Collateral Agent and the Lenders;
- (g) certified copies, dated as of date no earlier than thirty (30) days prior to the Effective Date, of financing statement searches, as Collateral Agent shall request, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;
- (h) a duly executed legal opinion of counsel to Borrower dated as of the Effective Date;
- (i) evidence satisfactory to Collateral Agent and the Lenders that the insurance policies required by Section 6.5 hereof are in full force and effect, together with appropriate evidence showing loss payable and/or additional insured clauses or endorsements in favor of Collateral Agent, for the ratable benefit of the Lenders; and
- (j) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof

**3.2 Conditions Precedent to Initial Credit Extension.** Each Lender's obligation to make a Term A Loan is subject to the condition precedent that Collateral Agent and each Lender shall consent to or shall have received, in form and substance satisfactory to Collateral Agent and each Lender, such documents, and completion of such other matters, as Collateral Agent and each Lender may reasonably deem necessary or appropriate, including, without limitation:

- (a) original Loan Documents, each duly executed by Borrower and each Subsidiary, as applicable to the extent not delivered (and not required to be delivered) under Section 3.1;
- (b) duly executed original Secured Promissory Notes in favor of each Lender according to its Term A Loan Commitment Percentage;
- (c) the certificate(s) for the Shares, together with Assignment(s) Separate from Certificate, duly executed in blank;
- (d) the UK Share Pledge;
- (e) a landlord's consent executed in favor of Collateral Agent in respect of all of Borrower's and each Subsidiaries' leased locations that either comprise the headquarters of Borrower or any Subsidiary or at

which either the books or records of Borrower or any Subsidiary are maintained or where Collateral having a value in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) is maintained;

(f) a bailee waiver executed in favor of Collateral Agent in respect of each third party bailee where Borrower or any Subsidiary maintains Collateral having a value in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00); and

(g) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

**3.3 Conditions Precedent to all Credit Extensions.** The obligation of each Lender to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt by Collateral Agent of an executed Disbursement Letter in the form of Exhibit B attached hereto;

(b) the representations and warranties in Section 5 hereof shall be true, accurate and complete in all material respects on the date of the Disbursement Letter and on the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date, and no Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in Section 5 hereof are true, accurate and complete in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true, accurate and complete in all material respects as of such date;

(c) in such Lender's sole and reasonable discretion, there has not been any Material Adverse Change or any material adverse deviation by Borrower from the Annual Projections of Borrower presented to and accepted by Collateral Agent and each Lender;

(d) to the extent not delivered at the Effective Date, duly executed original Secured Promissory Notes, in number, form and content acceptable to each Lender, and in favor of each Lender according to its Commitment Percentage, with respect to each Credit Extension made by such Lender after the Effective Date; and

(e) payment of the fees and Lenders' Expenses then due as specified in Section 2.5 hereof.

**3.4 Covenant to Deliver.** Borrower agrees to deliver to Collateral Agent and the Lenders each item required to be delivered to Collateral Agent under this Agreement as a condition precedent to any Credit Extension. Borrower expressly agrees that a Credit Extension made prior to the receipt by Collateral Agent or any Lender of any such item shall not constitute a waiver by Collateral Agent or any Lender of Borrower's obligation to deliver such item, and any such Credit Extension in the absence of a required item shall be made in each Lender's sole discretion.

**3.5 Procedures for Borrowing.** Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan set forth in this Agreement, to obtain a Term Loan, Borrower shall notify the Lenders (which notice shall be irrevocable) by electronic mail, facsimile, or telephone by 12:00 noon Eastern time five (5) Business Days prior to the date the Term Loan is to be made. Together with any such electronic, facsimile or telephonic notification, Borrower shall deliver to the Lenders by electronic mail or facsimile a completed Disbursement Letter executed by a Responsible Officer or his or her designee. The Lenders may rely on any

telephone notice given by a person whom a Lender reasonably believes is a Responsible Officer or designee. On the Funding Date, each Lender shall credit and/or transfer (as applicable) to the Designated Deposit Account, an amount equal to its Term Loan Commitment.

#### **4. CREATION OF SECURITY INTEREST**

**4.1 Grant of Security Interest.** Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. Borrower represents, warrants, and covenants that the security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower, shall promptly notify Collateral Agent in a writing signed by Borrower, after Borrower becomes aware of such tort claim, as the case may be, of the general details thereof (and further details as may be required by Collateral Agent) and grant to Collateral Agent, for the ratable benefit of the Lenders, in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent.

If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as the Lenders' obligation to make Credit Extensions has terminated, Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower.

**4.2 Authorization to File Financing Statements.** Borrower hereby authorizes Collateral Agent to file financing statements or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights under the Loan Documents, including a notice that any disposition of the Collateral, except to the extent permitted by the terms of this Agreement, by Borrower, or any other Person, shall be deemed to violate the rights of Collateral Agent under the Code.

**4.3 Pledge of Collateral.** Borrower hereby pledges, assigns and grants to Collateral Agent, for the ratable benefit of the Lenders, a security interest in all the Shares, together with all proceeds and substitutions thereof, all cash, stock and other moneys and property paid thereon, all rights to subscribe for securities declared or granted in connection therewith, and all other cash and noncash proceeds of the foregoing, as security for the performance of the Obligations. On the Effective Date, or, to the extent not certificated as of the Effective Date, within twenty (20) days of the certification of any Shares, the certificate or certificates for the Shares will be delivered to Collateral Agent, accompanied by an instrument of assignment duly executed in blank by Borrower. To the extent required by the terms and conditions governing the Shares, Borrower shall cause the books of each entity whose Shares are part of the Collateral and any transfer agent to reflect the pledge of the Shares. Upon the occurrence and during the continuance of an Event of Default hereunder, Collateral Agent may effect the transfer of any securities included in the Collateral (including but not limited to the Shares) into the name of Collateral Agent and cause new (as applicable) certificates representing such securities to be issued in the name of Collateral Agent or its transferee. Borrower will execute and deliver such documents, and take or cause to be taken such actions, as Collateral Agent may reasonably request to perfect or continue the perfection of Collateral Agent's security interest in the Shares. Unless an Event of Default shall have occurred and be continuing, Borrower shall be entitled to exercise any voting rights with respect to the Shares and to give consents, waivers and ratifications in respect thereof, provided that no vote shall be cast or consent, waiver or ratification given or action taken which would be inconsistent with any of the terms of this Agreement or which would constitute or create any violation of any of such terms. All such rights to vote and give consents, waivers and ratifications shall terminate upon the occurrence and continuance of an Event of Default.

## 5. REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants to Collateral Agent and the Lenders as follows:

**5.1 Due Organization, Authorization: Power and Authority.** Borrower and each of its Subsidiaries is duly existing and in good standing as a Registered Organization in its jurisdictions of organization or formation and Borrower and each of its Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to have a Material Adverse Change. In connection with this Agreement, Borrower and each of its Subsidiaries has delivered to Collateral Agent a completed perfection certificate signed by an officer of Borrower or such Subsidiary (each as updated from time to time, as permitted hereunder, a “**Perfection Certificate**” and collectively, the “**Perfection Certificates**”). Borrower represents and warrants that (a) Borrower and each of its Subsidiaries’ exact legal name is that which is indicated on its respective Perfection Certificate and on the signature page of each Loan Document to which it is a party; (b) Borrower and each of its Subsidiaries is an organization of the type and is organized in the jurisdiction set forth on its respective Perfection Certificate; (c) each Perfection Certificate accurately sets forth each of Borrower’s and its Subsidiaries’ organizational identification number or accurately states that Borrower or such Subsidiary has none; (d) each Perfection Certificate accurately sets forth Borrower’s and each of its Subsidiaries’ place of business, or, if more than one, its chief executive office as well as Borrower’s and each of its Subsidiaries’ mailing address (if different than its chief executive office); (e) Borrower and each of its Subsidiaries (and each of its respective predecessors) have not, in the past five (5) years, changed its jurisdiction of organization, organizational structure or type, or any organizational number assigned by its jurisdiction; and (f) all other information set forth on the Perfection Certificates pertaining to Borrower and each of its Subsidiaries, is accurate and complete in all material respects (it being understood and agreed that Borrower and each of its Subsidiaries may from time to time update certain information in the Perfection Certificates (including the information set forth in clause (d) above) after the Effective Date to the extent permitted by one or more specific provisions in this Agreement); such updated Perfection Certificates subject to the review and approval of Collateral Agent. If Borrower or any of its Subsidiaries is not now a Registered Organization but later becomes one, Borrower shall notify Collateral Agent of such occurrence and provide Collateral Agent with such Person’s organizational identification number within five (5) Business Days of receiving such organizational identification number.

The execution, delivery and performance by Borrower and each of its Subsidiaries of the Loan Documents to which it is a party have been duly authorized, and do not (i) conflict with any of Borrower’s or such Subsidiaries’ organizational documents, including its respective Operating Documents, (ii) contravene, conflict with, constitute a default under or violate any material Requirement of Law applicable thereto, (iii) contravene, conflict or violate any applicable order, writ, judgment, injunction, decree, determination or award of any Governmental Authority by which Borrower or such Subsidiary, or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) or are being obtained pursuant to Section 6.1(b), or (v) constitute an event of default under any material agreement by which Borrower or any of such Subsidiaries, or their respective properties, is bound. Neither Borrower nor any of its Subsidiaries is in default under any agreement to which it is a party or by which it or any of its assets is bound in which such default could reasonably be expected to have a Material Adverse Change.

### **5.2 Collateral.**

(a) Borrower and each its Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any Deposit Accounts, Securities Accounts, Commodity Accounts or other investment accounts other than the Collateral Accounts or the other investment accounts, if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith (as the same may be updated from time to time, provided that any such updates shall

be in form and substance acceptable to Collateral Agent and each Lender, in its sole discretion) with respect of which Borrower or such Subsidiary has given Collateral Agent notice and taken such actions as are necessary to give Collateral Agent a perfected security interest therein. The Accounts are bona fide, existing obligations of the Account Debtors.

(b) On the Effective Date, and except as disclosed on the Perfection Certificate (i) the Collateral is not in the possession of any third party bailee (such as a warehouse), and (ii) no such third party bailee possesses components of the Collateral in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00). None of the components of the Collateral shall be maintained at locations other than as disclosed in the Perfection Certificates on the Effective Date or as permitted pursuant to Section 6.11.

(c) All Inventory is in all material respects of good and marketable quality, free from material defects.

(d) Borrower and each of its Subsidiaries is the sole owner of the Intellectual Property each respectively purports to own, free and clear of all Liens other than Permitted Liens. Except as noted on the Perfection Certificates, neither Borrower nor any of its Subsidiaries is a party to, nor is bound by, any material license or other material agreement with respect to which Borrower or such Subsidiary is the licensee that (i) prohibits or otherwise restricts Borrower or its Subsidiaries from granting a security interest in Borrower's or such Subsidiaries' interest in such material license or material agreement or any other property, or (ii) for which a default under or termination of could interfere with Collateral Agent's or any Lender's right to sell any Collateral. Borrower shall provide written notice to Collateral Agent and each Lender within ten (10) Business Days of Borrower or any of its Subsidiaries entering into or becoming bound by any license or agreement with respect to which Borrower or any Subsidiary is the licensee (other than over-the-counter software that is commercially available to the public).

**5.3 Litigation.** Except as disclosed (i) on the Perfection Certificates, or (ii) in accordance with Section 6.9 hereof, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Two Hundred Fifty Thousand Dollars (\$250,000.00).

**5.4 No Material Deterioration in Financial Condition; Financial Statements.** All consolidated financial statements for Borrower and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Borrower and its Subsidiaries, and the consolidated results of operations of Borrower and its Subsidiaries as of the dates and for the periods presented. Lender understands that interim financial statements may not be audited and may be subject to normal year-end adjustments and the absence of footnotes; provided, however, that such adjustments shall not be material and in the case of revenues and cash balances such adjustments shall not be in excess of de minimis amounts. There has not been any material deterioration in the consolidated financial condition of Borrower and its Subsidiaries since the date of the most recent financial statements submitted to any Lender.

**5.5 Solvency.** Borrower is Solvent and Borrower and its Subsidiaries, on a consolidated basis, are Solvent.

**5.6 Regulatory Compliance.** Neither Borrower nor any of its Subsidiaries is an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Neither Borrower nor any of its Subsidiaries is engaged as one of its important activities in extending credit for margin stock (under Regulations X, T and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries has complied in all material respects with the Federal Fair Labor Standards Act. Neither Borrower nor any of its Subsidiaries is a "holding company" or an "affiliate" of a "holding company" or a "subsidiary company" of a "holding company" as each term is defined and used in the Public Utility Holding Company Act of 2005. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the

violation of which could reasonably be expected to have a Material Adverse Change. Neither Borrower's nor any of its Subsidiaries' properties or assets has been used by Borrower or such Subsidiary or, to Borrower's knowledge, by previous Persons, in disposing, producing, storing, treating, or transporting any hazardous substance other than in material compliance with applicable laws. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted.

None of Borrower, any of its Subsidiaries, or any of Borrower's or its Subsidiaries' Affiliates or any of their respective agents acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement is (i) in violation of any Anti-Terrorism Law, (ii) engaging in or conspiring to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding or attempts to violate, any of the prohibitions set forth in any Anti-Terrorism Law, or (iii) is a Blocked Person. None of Borrower, any of its Subsidiaries, or to the knowledge of Borrower and any of their Affiliates or agents, acting or benefiting in any capacity in connection with the transactions contemplated by this Agreement, (x) conducts any business or engages in making or receiving any contribution of funds, goods or services to or for the benefit of any Blocked Person, or (y) deals in, or otherwise engages in any transaction relating to, any property or interest in property blocked pursuant to Executive Order No. 13224, any similar executive order or other Anti-Terrorism Law.

**5.7 Investments.** Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

**5.8 Tax Returns and Payments; Pension Contributions.** Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower and each of its Subsidiaries, has timely paid all foreign, federal, state, and material local taxes, assessments, deposits and contributions (i.e. local taxes, assessments, deposits and contributions in an aggregate amount of \$50,000 or more) owed by Borrower and such Subsidiaries, in all jurisdictions in which Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in accordance with the following sentence. Borrower and each of its Subsidiaries, may defer payment of any contested taxes, provided that Borrower or such Subsidiary, (a) in good faith contests its obligation to pay the taxes by appropriate proceedings promptly and diligently instituted and conducted, (b) notifies Collateral Agent in writing of the commencement of, and any material development in, the proceedings, and (c) posts bonds or takes any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "**Permitted Lien.**" Neither Borrower nor any of its Subsidiaries is aware of any claims or adjustments proposed for any of Borrower's or such Subsidiaries', prior tax years which could result in additional taxes becoming due and payable by Borrower or its Subsidiaries. Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries have, withdrawn from participation in, and have not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**5.9 Use of Proceeds.** Borrower shall use the proceeds of the Credit Extensions solely as working capital and to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

**5.10 Shares.** Borrower has full power and authority to create a first lien on the Shares and no disability or contractual obligation exists that would prohibit Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. The Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened in writing suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

**5.11 Full Disclosure.** No written representation, warranty or other statement of Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that the projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

**5.12 Definition of "Knowledge."** For purposes of the Loan Documents, whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of the Responsible Officers.

## **6. AFFIRMATIVE COVENANTS**

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

### **6.1 Government Compliance.**

(a) Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change. Comply with all laws, ordinances and regulations to which Borrower or any of its Subsidiaries is subject, the noncompliance with which could reasonably be expected to have a Material Adverse Change. Notwithstanding anything herein to the contrary, Parent shall be permitted to dissolve Aclaris Life Sciences, Inc. (the "**Permitted Dissolution**"); provided, however, in connection with the Permitted Dissolution, (i) the parties shall enter into an amendment hereto, in such form and substance as are acceptable to Collateral Agent and Lenders in their discretion to remove ALS as a Borrower from the Loan Documents and the Parent shall cause all assets of ALS, after payment of reasonable costs in connection with the Permitted Dissolution, to be transferred to another Borrower and (ii) CDT will become a directly wholly owned Subsidiary of Parent.

(b) Obtain and keep in full force and effect, all of the material Governmental Approvals necessary for the performance by Borrower and its Subsidiaries of their respective businesses and obligations under the Loan Documents and the grant of a security interest to Collateral Agent for the ratable benefit of the Lenders, in all of the Collateral. Borrower shall promptly provide copies to Collateral Agent of any material Governmental Approvals obtained by Borrower or any of its Subsidiaries.

### **6.2 Financial Statements, Reports, Certificates.**

(a) Deliver to each Lender:

(i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated balance sheet, income statement and cash flow statement covering the consolidated operations of Parent and its Subsidiaries, on a consolidated basis, for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent;

(ii) as soon as available, but no later than one hundred twenty (120) days after the last day of Parent's fiscal year or within five (5) Business Days of filing with the SEC, audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm acceptable to Collateral Agent in its reasonable discretion; provided that such unqualified opinion may include a going concern explanatory paragraph;

(iii) as soon as available after approval thereof by Parent's Board of Directors, but no later than sixty (60) days after the last day of each of Parent's fiscal years, Parent's annual financial projections for the entire current fiscal year as approved by Parent's Board of Directors, which such annual financial projections shall be set forth in a quarter-by-quarter format (such annual financial projections as originally delivered to Collateral Agent and the Lenders are referred to herein as the "**Annual Projections**"; provided that, any revisions of the Annual Projections approved by Parent's Board of Directors shall be delivered to Collateral Agent and the Lenders no later than seven (7) Business Days after such approval);

(iv) within five (5) Business Days of delivery, copies of all material written statements, reports and notices made generally available to Parent's security holders or holders of Subordinated Debt;

(v) within five (5) Business Days of filing, all reports on Form 10-K, 10-Q and 8-K filed with the Securities and Exchange Commission,

(vi) prompt notice of any amendments or other changes to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto;

(vii) prompt notice of any event that could reasonably be expected to materially and adversely affect the value of the Intellectual Property;

(viii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month-end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s), and

(ix) other information as reasonably requested by Collateral Agent or any Lender.

Notwithstanding the foregoing, documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and if so delivered, shall be deemed to have been delivered on the date on which Borrower posts such documents, or provides a link thereto, on Borrower's website on the internet at Borrower's website address.

(b) Concurrently with the delivery of the financial statements specified in Section 6.2(a)(i) above but no later than thirty (30) days after the last day of each month, deliver to each Lender, a duly completed Compliance Certificate signed by a Responsible Officer.

(c) Keep proper books of record and account in accordance with GAAP in all material respects, in which full, true and correct entries shall be made of all dealings and transactions in relation to its business and activities. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than twice every year unless (and more frequently if) an Event of Default has occurred and is continuing.

**6.3 Inventory; Returns.** Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective Account Debtors, shall follow Borrower's, or such Subsidiary's practices that exist at the Effective Date or that may be implemented in the reasonable judgment of management. Borrower must promptly notify Collateral Agent and the

Lenders of all returns, recoveries, disputes and claims that involve more than Two Hundred Fifty Thousand Dollars (\$250,000.00) individually or in the aggregate in any calendar year.

**6.4 Taxes; Pensions.** Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports or extensions therefor (which are timely filed and accepted and approved by the applicable Governmental Authority) and timely pay, and require each of its Subsidiaries to timely file, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except for deferred payment of any taxes contested pursuant to the terms of Section 5.8 hereof, and shall deliver to Lenders, on demand, appropriate certificates attesting to such payments, and pay all amounts necessary to fund all present pension, profit sharing and deferred compensation plans in accordance with the terms of such plans.

**6.5 Insurance.** Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request. Insurance policies shall be in a form, with companies, and in amounts that are reasonably satisfactory to Collateral Agent and Lenders. All property policies shall have a lender's loss payable endorsement showing Collateral Agent as lender loss payee and waive subrogation against Collateral Agent, and all liability policies shall show, or have endorsements showing, Collateral Agent, as additional insured. The Collateral Agent shall be named as lender loss payee and/or additional insured with respect to any such insurance providing coverage in respect of any Collateral, and each provider of any such insurance shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to the Collateral Agent, that it will give the Collateral Agent thirty (30) days (ten (10) days for nonpayment of premium) prior written notice before any such policy or policies shall be canceled. At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments. Proceeds payable under any policy shall, at Collateral Agent's option, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying the proceeds of any casualty policy up to Five Hundred Thousand Dollars (\$500,000.00) with respect to any loss, but not exceeding Five Hundred Thousand Dollars (\$500,000.00), in the aggregate for all losses under all casualty policies in any one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Collateral Agent has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Collateral Agent, be payable to Collateral Agent, for the ratable benefit of the Lenders, on account of the Obligations. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make, at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

**6.6 Operating Accounts.**

(a) Maintain all of Borrower's and each Subsidiary's Collateral Accounts in accounts which are subject to a Control Agreement in favor of Collateral Agent other than Excluded Accounts.

(b) Borrower shall provide Collateral Agent five (5) Business Days' prior written notice before Borrower or any Subsidiary establishes any Collateral Account. In addition, for each Collateral Account (other than Excluded Accounts) that Borrower or any Loan Party, at any time maintains, Borrower or such Loan Party shall cause the applicable bank or financial institution at or with which such Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Collateral Agent's Lien in such Collateral Account in accordance with the terms hereunder prior to the establishment of such Collateral Account, which Control Agreement may not be terminated without prior written consent of Collateral Agent. The provisions of the previous sentence shall not apply to Excluded Accounts.

(c) Borrower shall not maintain any Collateral Accounts except Collateral Accounts maintained in accordance with Sections 6.6(a) and (b).

**6.7 Protection of Intellectual Property Rights.** Borrower and each of its Subsidiaries shall: (a) use commercially reasonable efforts to protect, defend and maintain the validity and enforceability of its Intellectual Property that is material to Borrower's business; (b) promptly advise Collateral Agent in writing of material infringement by a third party of its Intellectual Property; and (c) not allow any Intellectual Property material to Borrower's business to be abandoned, forfeited or dedicated to the public without Collateral Agent's prior written consent.

**6.8 Litigation Cooperation.** Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's Books, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third-party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

**6.9 Notices of Litigation and Default.** Borrower will give prompt written notice to Collateral Agent and the Lenders of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of Two Hundred Fifty Thousand Dollars (\$250,000.00) or more or which could reasonably be expected to have a Material Adverse Change. Without limiting or contradicting any other more specific provision of this Agreement, promptly (and in any event within five (5) Business Days) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, Borrower shall give written notice to Collateral Agent and the Lenders of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default.

**6.10 Financial Covenant.** Parent shall achieve the following:

(a) As tested on [\*\*\*], consolidated revenues for Parent and its Subsidiaries from the sale of the products of Parent and its Subsidiaries on a consolidated basis [\*\*\*];

(b) As tested on [\*\*\*], consolidated revenues for Parent and its Subsidiaries from the sale of the products of Parent and its Subsidiaries on a consolidated basis [\*\*\*]; and

(c) As tested on [\*\*\*], consolidated revenues for Parent and its Subsidiaries from the sale of products of Parent and its Subsidiaries on a consolidated basis [\*\*\*].

**6.11 Landlord Waivers; Bailee Waivers.** In the event that Borrower or any of its Subsidiaries, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2, then Borrower or such Subsidiary will first receive the written consent of Collateral Agent and, in the event that the new location is the chief executive office of the Borrower or a Loan Party or the Collateral at any such new location is valued in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate, such bailee or landlord, as applicable, must execute and deliver a bailee waiver or landlord waiver, as applicable, in form and substance reasonably satisfactory to Collateral Agent prior to the addition of any new offices or business locations, or any such storage with or delivery to any such bailee, as the case may be.

**6.12 Creation/Acquisition of Subsidiaries.** In the event Borrower, or any of its Subsidiaries creates or acquires any Subsidiary, Borrower shall provide prior written notice to Collateral Agent and each Lender of the creation or acquisition of such new Subsidiary and take all such action as may be reasonably required by Collateral

Agent or any Lender to cause each such Subsidiary to become a co-Borrower hereunder or to guarantee the Obligations of Borrower under the Loan Documents and, in each case, grant a continuing pledge and security interest in and to the assets of such Subsidiary (substantially as described on Exhibit A hereto); and Borrower (or its Subsidiary, as applicable) shall grant and pledge to Collateral Agent, for the ratable benefit of the Lenders, a perfected security interest in the Shares; provided, however, that solely in the circumstance in which Borrower or any Subsidiary creates or acquires a Foreign Subsidiary in an acquisition permitted by Section 7.7 hereof or otherwise approved by the Required Lenders, (i) such Foreign Subsidiary shall not be required to guarantee the Obligations of Borrower under the Loan Documents and grant a continuing pledge and security interest in and to the assets of such Foreign Subsidiary, and (ii) Borrower shall not be required to grant and pledge to Collateral Agent, for the ratable benefit of Lenders, a perfected security interest in more than sixty-five percent (65%) of the Shares of such Foreign Subsidiary, if Borrower demonstrates to the reasonable satisfaction of Collateral Agent that such Foreign Subsidiary providing such guarantee or pledge and security interest (other than as a co-Borrower) or Borrower providing a perfected security interest in more than sixty-five percent (65%) of the Shares would create a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code.

### **6.13 Further Assurances.**

(a) Execute any further instruments and take further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement.

(b) Deliver to Collateral Agent and Lenders, within five (5) Business Days after the same are sent or received, copies of all material correspondence, reports, documents and other filings with any Governmental Authority that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals material to Borrower's business or otherwise could reasonably be expected to have a Material Adverse Change.

## **7. NEGATIVE COVENANTS**

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

**7.1 Dispositions.** Convey, sell, lease, transfer, assign, or otherwise dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn out, surplus or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments and Permitted Licenses; (d) from any Subsidiary of Borrower to Borrower or between Borrowers; (e) consisting of payment of reasonable expenses in connection with the Permitted Dissolution, and (h) of property (other than Intellectual Property) having a book value not exceeding exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate during any fiscal year.

**7.2 Changes in Business, Management, Ownership, or Business Locations.** (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve other than the Permitted Dissolution; or (c) (i) any Key Person shall cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent within five (5) days after the relevant SEC filing of such change, or (ii) enter into any transaction or series of related transactions in which the stockholders of Borrower who were not stockholders immediately prior to the first such transaction own more than forty nine percent (49%) of the voting stock of Borrower immediately after giving effect to such transaction or related series of such transactions (other than by the sale of Borrower's equity securities in a public offering, a private placement of public equity or to venture capital investors so long as Borrower identifies to Collateral Agent the venture capital investors prior to the closing of the transaction). Borrower shall not, without at least thirty (30) days' prior written notice to Collateral Agent: (A) add any new offices or business locations, including warehouses (unless such new offices or business locations (i) contain less than Two Hundred Fifty Thousand Dollars (\$250,000.00) in assets or property of

Borrower; and (ii) are not Borrower's or any Loan Party's chief executive office); (B) change its jurisdiction of organization, (C) change its organizational structure or type, (D) change its legal name, or (E) change any organizational number (if any) assigned by its jurisdiction of organization.

**7.3 Mergers or Acquisitions.** Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the capital stock, shares or property of another Person other than pursuant to a Permitted Investment. A Subsidiary may merge or consolidate into another Subsidiary (provided such surviving Subsidiary is a "co-Borrower" hereunder or has provided a secured Guaranty of Borrower's Obligations hereunder) or with (or into) Borrower provided Borrower is the surviving legal entity, and as long as no Event of Default is occurring prior thereto or arises as a result therefrom. Without limiting the foregoing, Borrower shall not, without Collateral Agent's prior written consent, enter into any binding contractual arrangement with any Person to attempt to facilitate a merger or acquisition of Borrower, unless (i) no Event of Default exists when such agreement is entered into by Borrower, (ii) such agreement does not give such Person the right to claim any fees, payments or damages from Borrower in excess of Five Hundred Thousand Dollars (\$500,000.00) as a result of any failure to proceed with or close such merger or acquisition and (iii) Borrower notifies Collateral Agent in advance of entering into such an agreement.

**7.4 Indebtedness.** Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

**7.5 Encumbrance.** Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority security interest granted herein (except for Permitted Liens that are permitted by the terms of this Agreement to have priority over Collateral Agent's Lien), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property, except as is otherwise permitted in Section 7.1 hereof and the definition of "Permitted Liens" herein.

**7.6 Maintenance of Collateral Accounts.** Maintain any Collateral Account except pursuant to the terms of Section 6.6 hereof.

**7.7 Distributions; Investments.** (a) Pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock except that Borrower or any Subsidiary may (i) repurchase the stock of current or former employees, officers, directors or consultants, (ii) repurchase the stock of current or former employees, officers, directors or consultants pursuant to stock repurchase agreements by the cancellation of indebtedness owed by such former employees regardless of whether an Event of Default exists, (iii) purchase for value of any rights distributed in connection with any stockholder rights plan, (iv) purchases of capital stock or options to acquire such capital stock with the proceeds received from a substantially concurrent issuance of capital stock or convertible securities; (v) purchases of capital stock pledged as collateral for loans to employees, officers or directors; (vi) purchases of capital stock in connection with (x) the exercise of stock options or stock appreciation rights or (y) the satisfaction of withholding tax obligations; in each case, by way of cashless (or, "net") exercise; (vii) cash payments in lieu of the issuance of fractional shares upon conversion of convertible securities; and (viii) repurchases of stock pursuant to rights of first refusal in Borrowers' bylaws; so long as such repurchases and purchases (described in (i) through (viii)) do not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate per fiscal year; or (b) directly or indirectly make any Investment other than Permitted Investments, or permit any of its Subsidiaries to do so.

**7.8 Transactions with Affiliates.** Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower or any of its Subsidiaries, except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less

favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries, (c) any transaction expressly allowed under Section 7.1, (d) compensation and indemnification of, and other employment arrangements with, directors, officers and employees of Borrower or any Subsidiary, in each case, entered into in the ordinary course of business in accordance with Borrower's Annual Projections and corporate governance practices, (e) loans and advances otherwise explicitly permitted hereunder to be made to the applicable Affiliate, (f) intercompany services agreement between Borrowers, and (g) transactions disclosed in the Borrower's Perfection Certificates on the Effective Date (and without any amendments to the terms of such transactions which amendments would constitute such incremental or new transactions as would require consent of the Required Lenders or Collateral Agent hereunder).

**7.9 Subordinated Debt.** (a) Make or permit any payment on any Subordinated Debt, except under the terms of the subordination, intercreditor, or other similar agreement to which such Subordinated Debt is subject, or (b) amend any provision in any document relating to the Subordinated Debt which would increase the amount thereof or adversely affect the subordination thereof to Obligations owed to the Lenders.

**7.10 Compliance.** Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; fail to meet the minimum funding requirements of ERISA, permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur; fail to comply with the Federal Fair Labor Standards Act or violate any other law or regulation, if the violation could reasonably be expected to have a Material Adverse Change, or permit any of its Subsidiaries to do so; withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing and deferred compensation plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

**7.11 Compliance with Anti-Terrorism Laws.** Collateral Agent hereby notifies Borrower and each of its Subsidiaries that pursuant to the requirements of Anti-Terrorism Laws, and Collateral Agent's policies and practices, Collateral Agent is required to obtain, verify and record certain information and documentation that identifies Borrower and each of its Subsidiaries and their principals, which information includes the name and address of Borrower and each of its Subsidiaries and their principals and such other information that will allow Collateral Agent to identify such party in accordance with Anti-Terrorism Laws. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries permit any Affiliate to, directly or indirectly, knowingly enter into any documents, instruments, agreements or contracts with any Person listed on the OFAC Lists. Borrower and each of its Subsidiaries shall immediately notify Collateral Agent if Borrower or such Subsidiary has knowledge that Borrower, or any Subsidiary or Affiliate of Borrower, is listed on the OFAC Lists or (a) is convicted on, (b) pleads *nolo contendere* to, (c) is indicted on, or (d) is arraigned and held over on charges involving money laundering or predicate crimes to money laundering. Neither Borrower nor any of its Subsidiaries shall, nor shall Borrower or any of its Subsidiaries, permit any Affiliate to, directly or indirectly, (i) conduct any business or engage in any transaction or dealing with any Blocked Person, including, without limitation, the making or receiving of any contribution of funds, goods or services to or for the benefit of any Blocked Person, (ii) deal in, or otherwise engage in any transaction relating to, any property or interests in property blocked pursuant to Executive Order No. 13224 or any similar executive order or other Anti-Terrorism Law, or (iii) engage in or conspire to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in Executive Order No. 13224 or other Anti-Terrorism Law.

**7.12 UK Subsidiary Assets.** Allow the cash and Cash Equivalent assets held by the UK Subsidiary to exceed Two Million Dollars (\$2,000,000.00) at any given time.

## 8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an “**Event of Default**”) under this Agreement:

**8.1 Payment Default.** Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within three (3) Business Days after such Obligations are due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1(a) hereof). During the cure period, the failure to cure the payment default is not an Event of Default (but no Credit Extension will be made during the cure period);

### **8.2 Covenant Default.**

(a) Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes), 6.5 (Insurance), 6.6 (Operating Accounts), 6.7 (Protection of Intellectual Property Rights), 6.9 (Notice of Litigation and Default), 6.10 (Financial Covenant), 6.11 (Landlord Waivers; Bailee Waivers), 6.12 (Creation/Acquisition of Subsidiaries) or 6.13 (Further Assurances) or Borrower violates any covenant in Section 7; or

(b) Borrower, or any of its Subsidiaries, fails or neglects to perform, keep, or observe any other term, provision, condition, covenant or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 8) under such other term, provision, condition, covenant or agreement that can be cured, has failed to cure the default within twenty (20) days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the twenty (20) day period or cannot after diligent attempts by Borrower be cured within such twenty (20) day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which additional period shall not in any case exceed thirty (30) days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Grace periods provided under this Section shall not apply, among other things, to financial covenants or any other covenants set forth in subsection (a) above;

**8.3 Material Adverse Change.** A Material Adverse Change occurs;

### **8.4 Attachment; Levy; Restraint on Business.**

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any Lender or any Lender’s Affiliate or any bank or other institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any ten (10) day cure period; and

(b) (i) any material portion of Borrower’s or any of its Subsidiaries’ assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

**8.5 Insolvency.** (a) Borrower is or becomes insolvent or Borrower and its Subsidiaries, taken as a whole, are or become Insolvent; (b) Borrower or any of its Subsidiaries begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower or any of its Subsidiaries and not dismissed or stayed within forty-five (45) days (but no Credit Extensions shall be made while Borrower or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

**8.6 Other Agreements.** There is a default in any agreement to which Borrower or any of its Subsidiaries is a party with a third party or parties resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount in excess of Two Hundred Fifty Thousand Dollars (\$250,000.00) or that could reasonably be expected to have a Material Adverse Change; provided, however, that the Event of Default under this Section 8.6 caused by the occurrence of a breach or default under such other agreement shall be cured or waived for purposes of this Agreement upon Collateral Agent receiving written notice from the party asserting such breach or default of such cure or waiver of the breach or default under such other agreement, if at the time of such cure or waiver under such other agreement (x) Collateral Agent or any Lender has not declared an Event of Default under this Agreement and/or exercised any rights with respect thereto; (y) any such cure or waiver does not result in an Event of Default under any other provision of this Agreement or any Loan Document; and (z) in connection with any such cure or waiver under such other agreement, the terms of any agreement with such third party are not modified or amended in any manner which could in the good faith business judgment of Collateral Agent be materially less advantageous to Borrower;

**8.7 Judgments.** One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Two Hundred Fifty Thousand Dollars (\$250,000.00) (not covered by independent third party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of ten (10) days after the entry thereof (provided that no Credit Extensions will be made prior to the satisfaction, vacation, or stay of such judgment, order or decree);

**8.8 Misrepresentations.** Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made;

**8.9 Subordinated Debt.** A default or breach occurs under any agreement between Borrower or any of its Subsidiaries and any creditor of Borrower or any of its Subsidiaries that signed a subordination, intercreditor, or other similar agreement with Collateral Agent or the Lenders, or any creditor that has signed such an agreement with Collateral Agent or the Lenders breaches any terms of such agreement;

**8.10 Guaranty.** (a) Any Guaranty terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any Guaranty; (c) any circumstance described in Sections 8.3, 8.4, 8.5, 8.7, or 8.8 occurs with respect to any Guarantor, or (d) the liquidation, winding up, or termination of existence of any Guarantor;

**8.11 Governmental Approvals.** Any Governmental Approval shall have been revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term *and* such revocation, rescission, suspension, modification or non-renewal has resulted in or could reasonably be expected to result in a Material Adverse Change; or

**8.12 Lien Priority.** Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens which are permitted to have priority in accordance with the terms of this Agreement.

**8.13 Delisting.** The shares of common stock of Borrower are delisted from NASDAQ Stock Market because of failure to comply with continued listing standards thereof or due to a voluntary delisting which results in such shares not being listed on any other nationally recognized stock exchange in the United States having listing standards at least as restrictive as the NASDAQ Stock Market.

9. **RIGHTS AND REMEDIES**

9.1 **Rights and Remedies.**

(a) Upon the occurrence and during the continuance of an Event of Default, Collateral Agent may, and at the written direction of Required Lenders shall, without notice or demand, do any or all of the following: (i) deliver notice of the Event of Default to Borrower, (ii) by notice to Borrower declare all Obligations immediately due and payable (but if an Event of Default described in Section 8.5 occurs all Obligations shall be immediately due and payable without any action by Collateral Agent or the Lenders) or (iii) by notice to Borrower suspend or terminate the obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders (but if an Event of Default described in Section 8.5 occurs all obligations, if any, of the Lenders to advance money or extend credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Collateral Agent and/or the Lenders shall be immediately terminated without any action by Collateral Agent or the Lenders).

(b) Without limiting the rights of Collateral Agent and the Lenders set forth in Section 9.1(a) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) foreclose upon and/or sell or otherwise liquidate, the Collateral;

(ii) apply to the Obligations any (a) balances and deposits of Borrower that Collateral Agent or any Lender holds or controls, or (b) any amount held or controlled by Collateral Agent or any Lender owing to or for the credit or the account of Borrower; and/or

(iii) commence and prosecute an Insolvency Proceeding or consent to Borrower commencing any Insolvency Proceeding.

(c) Without limiting the rights of Collateral Agent and the Lenders set forth in Sections 9.1(a) and (b) above, upon the occurrence and during the continuance of an Event of Default, Collateral Agent shall have the right, without notice or demand, to do any or all of the following:

(i) settle or adjust disputes and claims directly with Account Debtors for amounts on terms and in any order that Collateral Agent considers advisable, notify any Person owing Borrower money of Collateral Agent's security interest in such funds, and verify the amount of such account;

(ii) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Collateral Agent requests and make it available in a location as Collateral Agent reasonably designates. Collateral Agent may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Collateral Agent a license to enter and occupy any of its premises, without charge, to exercise any of Collateral Agent's rights or remedies;

(iii) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, and/or advertise for sale, the Collateral. Collateral Agent is hereby granted a non-exclusive, royalty-free license or other right to use, without charge, Borrower's and each of its Subsidiaries' labels, patents, copyrights, mask works, rights of use of any name, trade secrets, trade names, trademarks, service marks, and advertising matter, or any similar property as it pertains to the Collateral, in completing production of, advertising for sale, and selling any Collateral and, in connection with Collateral Agent's exercise of its rights under this Section 9.1, Borrower's and each of its

Subsidiaries' rights under all licenses and all franchise agreements inure to Collateral Agent, for the benefit of the Lenders;

(iv) place a "hold" on any account maintained with Collateral Agent or the Lenders and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(v) demand and receive possession of Borrower's Books;

(vi) appoint a receiver to seize, manage and realize any of the Collateral, and such receiver shall have any right and authority as any competent court will grant or authorize in accordance with any applicable law, including any power or authority to manage the business of Borrower or any of its Subsidiaries; and

(vii) subject to clauses 9.1(a) and (b), exercise all rights and remedies available to Collateral Agent and each Lender under the Loan Documents or at law or equity, including all remedies provided under the Code (including disposal of the Collateral pursuant to the terms thereof).

Notwithstanding any provision of this Section 9.1 to the contrary, upon the occurrence of any Event of Default, Collateral Agent shall have the right to exercise any and all remedies referenced in this Section 9.1 without the written consent of Required Lenders following the occurrence of an Exigent Circumstance. As used in the immediately preceding sentence, "Exigent Circumstance" means any event or circumstance that, in the reasonable judgment of Collateral Agent, imminently threatens the ability of Collateral Agent to realize upon all or any material portion of the Collateral, such as, without limitation, fraudulent removal, concealment, or abscondment thereof, destruction or material waste thereof, or failure of Borrower or any of its Subsidiaries after reasonable demand to maintain or reinstate adequate casualty insurance coverage, or which, in the judgment of Collateral Agent, could reasonably be expected to result in a material diminution in value of the Collateral.

**9.2 Power of Attorney.** Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney-in-fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney-in-fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full and Collateral Agent and the Lenders are under no further obligation to make Credit Extensions hereunder. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed and Collateral Agent's and the Lenders' obligation to provide Credit Extensions terminates.

**9.3 Protective Payments.** If Borrower or any of its Subsidiaries fail to obtain the insurance called for by Section 6.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower or any of its Subsidiaries is obligated to pay under this Agreement or any other Loan Document, Collateral Agent may obtain such insurance or make such payment, and all amounts so paid by Collateral Agent are Lenders' Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Collateral Agent will make reasonable efforts to provide Borrower with notice of Collateral Agent obtaining such insurance or

making such payment at the time it is obtained or paid or within a reasonable time thereafter. No such payments by Collateral Agent are deemed an agreement to make similar payments in the future or Collateral Agent's waiver of any Event of Default.

**9.4 Application of Payments and Proceeds.** Notwithstanding anything to the contrary contained in this Agreement, upon the occurrence and during the continuance of an Event of Default, (a) Borrower irrevocably waives the right to direct the application of any and all payments at any time or times thereafter received by Collateral Agent from or on behalf of Borrower or any of its Subsidiaries of all or any part of the Obligations, and, as between Borrower on the one hand and Collateral Agent and Lenders on the other, Collateral Agent shall have the continuing and exclusive right to apply and to reapply any and all payments received against the Obligations in such manner as Collateral Agent may deem advisable notwithstanding any previous application by Collateral Agent, and (b) the proceeds of any sale of, or other realization upon all or any part of the Collateral shall be applied: first, to the Lenders' Expenses; second, to accrued and unpaid interest on the Obligations (including any interest which, but for the provisions of the United States Bankruptcy Code, would have accrued on such amounts); third, to the principal amount of the Obligations outstanding; and fourth, to any other indebtedness or obligations of Borrower owing to Collateral Agent or any Lender under the Loan Documents. Any balance remaining shall be delivered to Borrower or to whoever may be lawfully entitled to receive such balance or as a court of competent jurisdiction may direct. In carrying out the foregoing, (x) amounts received shall be applied in the numerical order provided until exhausted prior to the application to the next succeeding category, and (y) each of the Persons entitled to receive a payment in any particular category shall receive an amount equal to its pro rata share of amounts available to be applied pursuant thereto for such category. Any reference in this Agreement to an allocation between or sharing by the Lenders of any right, interest or obligation "ratably," "proportionally" or in similar terms shall refer to Pro Rata Share unless expressly provided otherwise. Collateral Agent, or if applicable, each Lender, shall promptly remit to the other Lenders such sums as may be necessary to ensure the ratable repayment of each Lender's portion of any Term Loan and the ratable distribution of interest, fees and reimbursements paid or made by Borrower. Notwithstanding the foregoing, a Lender receiving a scheduled payment shall not be responsible for determining whether the other Lenders also received their scheduled payment on such date; provided, however, if it is later determined that a Lender received more than its ratable share of scheduled payments made on any date or dates, then such Lender shall remit to Collateral Agent or other Lenders such sums as may be necessary to ensure the ratable payment of such scheduled payments, as instructed by Collateral Agent. If any payment or distribution of any kind or character, whether in cash, properties or securities, shall be received by a Lender in excess of its ratable share, then the portion of such payment or distribution in excess of such Lender's ratable share shall be received by such Lender in trust for and shall be promptly paid over to the other Lender for application to the payments of amounts due on the other Lenders' claims. To the extent any payment for the account of Borrower is required to be returned as a voidable transfer or otherwise, the Lenders shall contribute to one another as is necessary to ensure that such return of payment is on a pro rata basis. If any Lender shall obtain possession of any Collateral, it shall hold such Collateral for itself and as agent and bailee for Collateral Agent and other Lenders for purposes of perfecting Collateral Agent's security interest therein.

**9.5 Liability for Collateral.** So long as Collateral Agent and the Lenders comply with reasonable banking practices regarding the safekeeping of the Collateral in the possession or under the control of Collateral Agent and the Lenders, Collateral Agent and the Lenders shall not be liable or responsible for: (a) the safekeeping of the Collateral; (b) any loss or damage to the Collateral; (c) any diminution in the value of the Collateral; or (d) any act or default of any carrier, warehouseman, bailee, or other Person. Borrower bears all risk of loss, damage or destruction of the Collateral.

**9.6 No Waiver; Remedies Cumulative.** Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan

Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

**9.7 Demand Waiver.** Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

## 10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower: ACLARIS THERAPEUTICS, INC.  
CONFLUENCE DISCOVERY  
TECHNOLOGIES, INC.  
ACLARIS LIFE SCIENCES, INC.  
640 Lee Road, Suite 200  
Wayne, PA 19087  
Attn: Kamil Ali-Jackson, Chief Legal Officer  
Email: kalijackson@aclaristx.com

with a copy (which shall not constitute notice) to: Cooley LLP  
101 California Street, 5<sup>th</sup> Floor  
San Francisco, CA 94111  
Attn: Maricel Mojares-Moore  
Fax: (415) 693-2222  
Email: mmoore@cooley.com

If to Collateral Agent: OXFORD FINANCE LLC  
133 North Fairfax Street  
Alexandria, Virginia 22314  
Attention: Legal Department  
Fax: (703) 519-5225  
Email: LegalDepartment@oxfordfinance.com

with a copy (which shall not constitute notice) to: Greenberg Traurig, LLP  
One International Place  
Boston, MA 02110  
Attn: Jonathan Bell  
Fax: (617) 310-6001  
Email: bellj@gtlaw.com

## 11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

New York law governs the Loan Documents without regard to principles of conflicts of law. Borrower, Lenders and Collateral Agent each submit to the exclusive jurisdiction of the State and Federal courts in the City of New York, Borough of Manhattan. NOTWITHSTANDING THE FOREGOING, COLLATERAL AGENT AND THE LENDERS SHALL HAVE THE RIGHT TO BRING ANY ACTION OR PROCEEDING AGAINST BORROWER OR ITS PROPERTY IN THE COURTS OF ANY OTHER JURISDICTION WHICH COLLATERAL AGENT AND THE LENDERS (IN ACCORDANCE WITH THE PROVISIONS OF SECTION 9.1) DEEM NECESSARY OR APPROPRIATE TO REALIZE ON THE COLLATERAL OR TO OTHERWISE ENFORCE COLLATERAL AGENT'S AND THE LENDERS' RIGHTS AGAINST BORROWER OR ITS PROPERTY. Borrower expressly submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby waives any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 10 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or three (3) days after deposit in the U.S. mails, first class, registered or certified mail return receipt requested, proper postage prepaid.

**TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER, COLLATERAL AGENT, AND THE LENDERS EACH WAIVE THEIR RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR EACH PARTY TO ENTER INTO THIS AGREEMENT. EACH PARTY HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.**

## 12. GENERAL PROVISIONS

**12.1 Successors and Assigns.** This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's and each Lender's prior written consent (which may be granted or withheld in Collateral Agent's and each Lender's discretion, subject to Section 12.6). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, the Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents; *provided, however*, that any such Lender Transfer (other than a transfer, pledge, sale or assignment to an Eligible Assignee) of its obligations, rights, and benefits under this Agreement and the other Loan Documents shall require the prior written consent of the Required Lenders (such approved assignee, an "**Approved Lender**"). Borrower and Collateral Agent shall be entitled to continue to deal solely and directly with such Lender in connection with the interests so assigned until Collateral Agent shall have received and accepted an effective assignment agreement in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee or Approved Lender as Collateral Agent reasonably shall require. Notwithstanding anything to the contrary contained herein, so long as no Event of Default has occurred and is continuing, no Lender Transfer (other than a Lender Transfer in connection with (x) assignments by a Lender due to a forced divestiture at the request of any regulatory agency; or (y) upon the occurrence of a default, event of default or similar occurrence with respect to a Lender's own financing or securitization transactions) shall be permitted, without Borrower's consent, to any Person which is an Affiliate or Subsidiary of Borrower, a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent.

**12.2 Indemnification.** Borrower agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective directors, officers, employees, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an “**Indemnified Person**”) harmless against: (a) all obligations, demands, claims, and liabilities (collectively, “**Claims**”) asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or Lenders’ Expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys’ fees and expenses), except for Claims and/or losses directly caused by such Indemnified Person’s gross negligence or willful misconduct. Borrower hereby further indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements directly caused by such Indemnified Person’s gross negligence or willful misconduct.

**12.3 Time of Essence.** Time is of the essence for the performance of all Obligations in this Agreement.

**12.4 Severability of Provisions.** Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

**12.5 Correction of Loan Documents.** Collateral Agent and the Lenders may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the parties.

**12.6 Amendments in Writing; Integration.** (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, or any consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender’s Term Loan Commitment or Commitment Percentage shall be effective as to such Lender without such Lender’s written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent’s written consent or signature;

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to any Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to any Term Loan (B) postpone the date fixed for, or waive, any payment of principal of any Term Loan or of interest on any Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term “**Required Lenders**” or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral or release any Guarantor of all or any portion of the

Obligations or its guaranty obligations with respect thereto, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.6 or the definitions of the terms used in this Section 12.6 insofar as the definitions affect the substance of this Section 12.6; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations; or (I) amend any of the provisions of Section 12.10. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the preceding sentence;

(iv) the provisions of the foregoing clauses (i), (ii) and (iii) are subject to the provisions of any interlender or agency agreement among the Lenders and Collateral Agent pursuant to which any Lender may agree to give its consent in connection with any amendment, waiver or modification of the Loan Documents only in the event of the unanimous agreement of all Lenders.

(b) Other than as expressly provided for in Section 12.6(a)(i)-(iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

**12.7 Counterparts.** This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement.

**12.8 Survival.** All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.9 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

**12.9 Confidentiality.** In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates, or in connection with a Lender's own financing or securitization transactions and upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Credit Extensions (provided, however, the Lenders and Collateral Agent shall, except upon the occurrence and during the continuance of an Event of Default, obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement with the Lenders and Collateral Agent

with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent through no fault of the Lenders and/or Collateral Agent in breach of this Agreement; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.9 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.9.

**12.10 Right of Set Off.** Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED.

**12.11 Cooperation of Borrower.** If necessary, Borrower agrees to (i) execute any documents (including new Secured Promissory Notes) reasonably required to effectuate and acknowledge each assignment of a Term Loan Commitment or Loan to an assignee in accordance with Section 12.1, (ii) make Borrower's management available to meet with Collateral Agent and prospective participants and assignees of Term Loan Commitments or Credit Extensions (which meetings shall be conducted no more often than twice every twelve months unless an Event of Default has occurred and is continuing), and (iii) assist Collateral Agent or the Lenders in the preparation of information relating to the financial affairs of Borrower as any prospective participant or assignee of a Term Loan Commitment or Term Loan reasonably may request. Subject to the provisions of Section 12.9, Borrower authorizes each Lender to disclose to any prospective participant or assignee of a Term Loan Commitment, any and all information in such Lender's possession concerning Borrower and its financial affairs which has been delivered to such Lender by or on behalf of Borrower pursuant to this Agreement, or which has been delivered to such Lender by or on behalf of Borrower in connection with such Lender's credit evaluation of Borrower prior to entering into this Agreement.

**12.12 Borrower Liability.** Either Borrower may, acting singly, request Credit Extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting Credit Extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all Credit Extensions made hereunder, regardless of which Borrower actually receives said Credit Extension, as if each Borrower hereunder directly received all Credit Extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other

Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section shall be null and void. If any payment is made to a Borrower in contravention of this Section, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

### 13. **DEFINITIONS**

**13.1 Definitions.** As used in this Agreement, the following terms have the following meanings:

“**Account**” is any “account” as defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to Borrower.

“**Account Debtor**” is any “account debtor” as defined in the Code with such additions to such term as may hereafter be made.

“**Acquisition Event**” is the acquisition by Borrower, before October 31, 2018, of RHOFADÉ®, on such terms and conditions as are satisfactory to Collateral Agent and Lenders in their discretion.

“**Affiliate**” of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person’s senior executive officers, directors, partners and, for any Person that is a limited liability company, that Person’s managers and members.

“**Agreement**” is defined in the preamble hereof.

“**Amortization Date**” is November 1, 2021.

“**Annual Projections**” is defined in Section 6.2(a).

“**Anti-Terrorism Laws**” are any laws relating to terrorism or money laundering, including Executive Order No. 13224 (effective September 24, 2001), the USA PATRIOT Act, the laws comprising or implementing the Bank Secrecy Act, and the laws administered by OFAC.

“**Approved Fund**” is any (i) investment company, fund, trust, securitization vehicle or conduit that is (or will be) engaged in making, purchasing, holding or otherwise investing in commercial loans and similar extensions of credit in the ordinary course of its business or (ii) any Person (other than a natural person) which temporarily warehouses loans for any Lender or any entity described in the preceding clause (i) and that, with respect to each of the preceding clauses (i) and (ii), is administered or managed by (a) a Lender, (b) an Affiliate of a Lender or (c) a Person (other than a natural person) or an Affiliate of a Person (other than a natural person) that administers or manages a Lender.

“**Approved Lender**” is defined in Section 12.1.

“**Basic Rate**” is with respect to any Term Loan, the per annum rate of interest (based on a year of three hundred sixty (360) days) equal to the greater of (a) Eight and Thirty-Five Hundredths percent (8.35%) and (b) the sum of (i) thirty (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 (ii) Six and Twenty-Five

Hundredths percent (6.25%). If The Wall Street Journal (or another nationally recognized rate reporting source acceptable to Collateral Agent) no longer reports the U.S. LIBOR Rate or if such interest rate no longer exists or if The Wall Street Journal no longer publishes the U.S. LIBOR Rate or ceases to exist, Collateral Agent may in good faith select a replacement interest rate or replacement publication, as the case may be.

“**Blocked Person**” is any Person: (a) listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (b) a Person owned or controlled by, or acting for or on behalf of, any Person that is listed in the annex to, or is otherwise subject to the provisions of, Executive Order No. 13224, (c) a Person with which any Lender is prohibited from dealing or otherwise engaging in any transaction by any Anti-Terrorism Law, (d) a Person that commits, threatens or conspires to commit or supports “terrorism” as defined in Executive Order No. 13224, or (e) a Person that is named a “specially designated national” or “blocked person” on the most current list published by OFAC or other similar list.

“**Borrower**” is defined in the preamble hereof.

“**Borrower’s Books**” are Borrower’s or any of its Subsidiaries’ books and records including ledgers, federal, and state tax returns, records regarding Borrower’s or its Subsidiaries’ assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

“**Business Day**” is any day that is not a Saturday, Sunday or a day on which Collateral Agent is closed.

“**Cash Equivalents**” are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor’s Ratings Group or Moody’s Investors Service, Inc., and (c) certificates of deposit maturing no more than one (1) year after issue provided that the account in which any such certificate of deposit is maintained is subject to a Control Agreement in favor of Collateral Agent. For the avoidance of doubt, the direct purchase by Borrower or any of its Subsidiaries of any Auction Rate Securities, or purchasing participations in, or entering into any type of swap or other derivative transaction, or otherwise holding or engaging in any ownership interest in any type of Auction Rate Security by Borrower or any of its Subsidiaries shall be conclusively determined by the Lenders as an ineligible Cash Equivalent, and any such transaction shall expressly violate each other provision of this Agreement governing Permitted Investments. Notwithstanding the foregoing, Cash Equivalents does not include and Borrower, and each of its Subsidiaries, are prohibited from purchasing, purchasing participations in, entering into any type of swap or other equivalent derivative transaction, or otherwise holding or engaging in any ownership interest in any type of debt instrument, including, without limitation, any corporate or municipal bonds with a long-term nominal maturity for which the interest rate is reset through a dutch auction and more commonly referred to as an auction rate security (each, an “**Auction Rate Security**”).

“**Claims**” are defined in Section 12.2.

“**Code**” is the Uniform Commercial Code, as the same may, from time to time, be enacted and in effect in the State of New York; provided, that, to the extent that the Code is used to define any term herein or in any Loan Document and such term is defined differently in different Articles or Divisions of the Code, the definition of such term contained in Article or Division 9 shall govern; provided further, that in the event that, by reason of mandatory provisions of law, any or all of the attachment, perfection, or priority of, or remedies with respect to, Collateral Agent’s Lien on any Collateral is governed by the Uniform Commercial Code in effect in a jurisdiction other than the State of New York, the term “Code” shall mean the Uniform Commercial Code as enacted and in effect in such other jurisdiction solely for purposes of the provisions thereof relating to such attachment, perfection, priority, or remedies and for purposes of definitions relating to such provisions.

“**Collateral**” is any and all properties, rights and assets of Borrower described on Exhibit A.

“**Collateral Account**” is any Deposit Account, Securities Account, or Commodity Account, or any other bank account maintained by Borrower or any Subsidiary at any time.

“**Collateral Agent**” is, Oxford, not in its individual capacity, but solely in its capacity as agent on behalf of and for the benefit of the Lenders.

“**Commitment Percentage**” is set forth in Schedule 1.1, as amended from time to time.

“**Commodity Account**” is any “commodity account” as defined in the Code with such additions to such term as may hereafter be made.

“**Communication**” is defined in Section 10.

“**Compliance Certificate**” is that certain certificate in the form attached hereto as Exhibit C.

“**Contingent Obligation**” is, for any Person, any direct or indirect liability, contingent or not, of that Person for (a) any indebtedness, lease, dividend, letter of credit or other obligation of another such as an obligation directly or indirectly guaranteed, endorsed, co-made, discounted or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (b) any obligations for undrawn letters of credit for the account of that Person; and (c) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates or commodity prices; but “Contingent Obligation” does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

“**Control Agreement**” is any control agreement entered into among the depository institution at which Borrower or any of its Subsidiaries maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower or any of its Subsidiaries maintains a Securities Account or a Commodity Account, Borrower and such Subsidiary, and Collateral Agent pursuant to which Collateral Agent obtains control (within the meaning of the Code) for the benefit of the Lenders over such Deposit Account, Securities Account, or Commodity Account.

“**Copyrights**” are any and all copyright rights, copyright applications, copyright registrations and like protections in each work or authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

“**Credit Extension**” is any Term Loan or any other extension of credit by Collateral Agent or Lenders for Borrower’s benefit.

“**Default Rate**” is defined in Section 2.3(b).

“**Deposit Account**” is any “deposit account” as defined in the Code with such additions to such term as may hereafter be made.

“**Designated Deposit Account**” is Borrower’s deposit account, account number 5609, maintained with Silicon Valley Bank.

“**Domestic Subsidiary**” is a Subsidiary that is an entity organized under the laws of the United States or any territory thereof.

“**Disbursement Letter**” is that certain form attached hereto as Exhibit B.

“**Dollars,**” “**dollars**” and “**\$**” each mean lawful money of the United States.

“**Effective Date**” is defined in the preamble of this Agreement.

“**Eligible Assignee**” is (i) a Lender, (ii) an Affiliate of a Lender, (iii) an Approved Fund and (iv) any commercial bank, savings and loan association or savings bank or any other entity which is an “accredited investor” (as defined in Regulation D under the Securities Act of 1933, as amended) and which extends credit or buys loans as one of its businesses, including insurance companies, mutual funds, lease financing companies and commercial finance companies, in each case, which either (A) has a rating of BBB or higher from Standard & Poor’s Rating Group and a rating of Baa2 or higher from Moody’s Investors Service, Inc. at the date that it becomes a Lender or (B) has total assets in excess of Five Billion Dollars (\$5,000,000,000.00), and in each case of clauses (i) through (iv), which, through its applicable lending office, is capable of lending to Borrower without the imposition of any withholding or similar taxes; provided that notwithstanding the foregoing, “Eligible Assignee” shall not include, unless an Event of Default has occurred and is continuing, (i) Borrower or any of Borrower’s Affiliates or Subsidiaries or (ii) a direct competitor of Borrower or a vulture hedge fund, each as determined by Collateral Agent. Notwithstanding the foregoing, (x) in connection with assignments by a Lender due to a forced divestiture at the request of any regulatory agency, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party and (y) in connection with a Lender’s own financing or securitization transactions, the restrictions set forth herein shall not apply and Eligible Assignee shall mean any Person or party providing such financing or formed to undertake such securitization transaction and any transferee of such Person or party upon the occurrence of a default, event of default or similar occurrence with respect to such financing or securitization transaction; provided that no such sale, transfer, pledge or assignment under this clause (y) shall release such Lender from any of its obligations hereunder or substitute any such Person or party for such Lender as a party hereto until Collateral Agent shall have received and accepted an effective assignment agreement from such Person or party in form satisfactory to Collateral Agent executed, delivered and fully completed by the applicable parties thereto, and shall have received such other information regarding such Eligible Assignee as Collateral Agent reasonably shall require.

“**Equipment**” is all “equipment” as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

“**ERISA**” is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

“**Event of Default**” is defined in Section 8.

“**Excluded Accounts**” means any (i) Deposit Accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower’s or its Subsidiaries employees, (ii) escrow accounts in which funds have been deposited by Borrower (and are yet to be released) to meet its obligations related to an acquisition by Borrower which has been consented to by Collateral Agent and Required Lenders, and (iii) Collateral Accounts of any Subsidiary that is not a Loan Party.

“**Final Payment**” is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Maturity Date, or (b) the acceleration of any Term Loan, or (c) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d), equal to the original principal amount of such funded Term Loan multiplied by the Final Payment Percentage, payable to Lenders in accordance with their respective Pro Rata Shares. For the avoidance of doubt, the calculation of any Final Payment shall not include the principal amount prepaid in accordance with Section 2.2(d)(ii) if a Final Payment based on such principal amount was made at the time of such prepayment.

**“Final Payment Percentage”** is Five and seventy-five hundredths percent (5.75%).

**“First Draw Period”** is the period commencing on the Effective Date and ending on the earlier of (i) October 31, 2018 and (ii) the occurrence of an Event of Default.

**“Foreign Subsidiary”** is a Subsidiary that is not an entity organized under the laws of the United States or any territory thereof.

**“Funding Date”** is any date on which a Credit Extension is made to or on account of Borrower which shall be a Business Day.

**“GAAP”** is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession in the United States, which are applicable to the circumstances as of the date of determination.

**“General Intangibles”** are all “general intangibles” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation, all copyright rights, copyright applications, copyright registrations and like protections in each work of authorship and derivative work, whether published or unpublished, any patents, trademarks, service marks and, to the extent permitted under applicable law, any applications therefor, whether registered or not, any trade secret rights, including any rights to unpatented inventions, payment intangibles, royalties, contract rights, goodwill, franchise agreements, purchase orders, customer lists, route lists, telephone numbers, domain names, claims, income and other tax refunds, security and other deposits, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance and rights to payment of any kind.

**“Governmental Approval”** is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing or notice, of, issued by, from or to, or other act by or in respect of, any Governmental Authority.

**“Governmental Authority”** is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative functions of or pertaining to government, any securities exchange and any self-regulatory organization.

**“Guarantor”** is any Person providing a Guaranty in favor of Collateral Agent.

**“Guaranty”** is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified or otherwise supplemented.

**“Indebtedness”** is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, and (d) Contingent Obligations.

**“Indemnified Person”** is defined in Section 12.2.

**“Insolvency Proceeding”** is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, or other relief.

“**Insolvent**” means not Solvent.

“**Intellectual Property**” means all of Borrower’s or any Subsidiary’s right, title and interest in and to the following:

- (a) its Copyrights, Trademarks and Patents;
- (b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, operating manuals;
- (c) any and all source code;
- (d) any and all design rights which may be available to Borrower;
- (e) any and all claims for damages by way of past, present and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and
- (f) all amendments, renewals and extensions of any of the Copyrights, Trademarks or Patents.

“**Inventory**” is all “inventory” as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person’s custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

“**Investment**” is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance, payment or capital contribution to any Person.

“**Key Person**” is each of Borrower’s (i) Chief Executive Officer, who is Dr. Neal Walker as of the Effective Date, and (ii) Chief Financial Officer, who is Frank Ruffo as of the Effective Date.

“**Lender**” is any one of the Lenders.

“**Lenders**” are the Persons identified on Schedule 1.1 hereto and each assignee that becomes a party to this Agreement pursuant to Section 12.1.

“**Lenders’ Expenses**” are all audit fees and expenses, costs, and expenses (including reasonable attorneys’ fees and expenses, as well as appraisal fees, fees incurred on account of lien searches, inspection fees, and filing fees) for preparing, amending, negotiating, administering, defending and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred by Collateral Agent and/or the Lenders in connection with the Loan Documents.

“**Lien**” is a claim, mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

“**Loan Party**” is any Borrower or Guarantor.

“**Loan Documents**” are, collectively, this Agreement, the Perfection Certificates, each Compliance Certificate, each Disbursement Letter, the UK Share Pledge, any subordination agreements, any note, or notes or

guaranties executed by Borrower or any other Person, and any other present or future agreement entered into by Borrower, any Guarantor or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified.

“**Material Adverse Change**” is (a) a material impairment in the perfection or priority of Collateral Agent’s Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations or condition (financial or otherwise) of Borrower or any Subsidiary; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

“**Maturity Date**” is, for each Term Loan, October 1, 2023.

“**Obligations**” are all of Borrower’s obligations to pay when due any debts, principal, interest, Lenders’ Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower’s duties under the Loan Documents.

“**OFAC**” is the U.S. Department of Treasury Office of Foreign Assets Control.

“**OFAC Lists**” are, collectively, the Specially Designated Nationals and Blocked Persons List maintained by OFAC pursuant to Executive Order No. 13224, 66 Fed. Reg. 49079 (Sept. 25, 2001) and/or any other list of terrorists or other restricted Persons maintained pursuant to any of the rules and regulations of OFAC or pursuant to any other applicable Executive Orders.

“**Operating Documents**” are, for any Person, (a) such Person’s formation documents, as certified by the Secretary of State (or equivalent agency) of such Person’s jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (b) (x) if such Person is a corporation, its bylaws in current form, (y) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (z) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

“**Parent**” is defined in the Recitals.

“**Patents**” means all patents, patent applications and like protections including without limitation improvements, divisions, continuations, renewals, reissues, extensions and continuations-in-part of the same.

“**Payment Date**” is the first (1<sup>st</sup>) calendar day of each calendar month, commencing on November 1, 2018.

“**Perfection Certificate**” and “**Perfection Certificates**” is defined in Section 5.1.

“**Permitted Dissolution**” is defined in Section 6.1.

“**Permitted Indebtedness**” is:

(a) Borrower’s Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s) (provided, however, the amount of such Indebtedness of the UK Subsidiary to the Parent on the Effective Date that shall be deemed to be Permitted Indebtedness pursuant to this clause (b) is only \$578,000);

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness consisting of capitalized lease obligations and purchase money Indebtedness, in each case incurred by Borrower or any of its Subsidiaries to finance the acquisition, repair, improvement or construction of fixed or capital assets of such person, provided that (i) the aggregate outstanding principal amount of all such Indebtedness does not exceed Five Hundred Thousand Dollars (\$500,000.00) at any time and (ii) the principal amount of such Indebtedness does not exceed the lower of the cost or fair market value of the property so acquired or built or of such repairs or improvements financed with such Indebtedness (each measured at the time of such acquisition, repair, improvement or construction is made); furthermore, notwithstanding anything to the contrary herein and strictly for the purposes of this clause (e) of the definition of Permitted Indebtedness and for no other purpose, any obligations of a Person that are or would have been treated as operating leases for purposes of GAAP prior to the issuance by the Financial Accounting Standards Board on February 25, 2016 of an Accounting Standards Update (the "ASU") shall continue to be accounted for as operating leases for purposes of all financial definitions, calculations and covenants for purpose of this Agreement (whether or not such operating lease obligations were in effect on such date) notwithstanding the fact that such obligations are required in accordance with the ASU (on a prospective or retroactive basis or otherwise) to be treated as capitalized lease obligations in accordance with GAAP;

(f) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of Borrower's business;

(g) Any obligations with respect to corporate credit cards or merchant services for the account of Borrower or any Subsidiary in an aggregate amount outstanding at any time not to exceed Seven Hundred Fifty Thousand Dollars (\$750,000.00);

(h) all obligations arising under any interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect Borrower or a Subsidiary against fluctuation in interest rates, currency exchange rates or commodity prices; provided the aggregate amount of Indebtedness under this clause (h) may not exceed One Hundred Thousand Dollars (\$100,000.00) at any given time;

(i) Indebtedness in respect of letters of credit, bank guarantees and similar instruments issued for the account of the Borrower or any Subsidiary in the ordinary course of business supporting obligations under (A) workers' compensation, unemployment insurance and other social security laws and (B) bids, trade contracts, leases, statutory obligations, surety and appeal bonds, performance bonds and obligations of a like nature; provided the aggregate amount of Indebtedness under this clause (i) may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any given time;

(j) Indebtedness constituting of Investments under clause (f) of the definition of "Permitted Investments" but without duplication;

(k) Indebtedness of a Person (other than Borrower or one of its Subsidiaries which constituted a Subsidiary prior to the consummation of the applicable merger referenced below) existing at the time such Person is merged with or into Borrower or a Subsidiary or becomes a Subsidiary as a result of the Acquisition Event; provided that (i) such Indebtedness was not, in any case, incurred by such other Person in connection with, or in contemplation of, the Acquisition Event, (ii) such merger or acquisition constitutes Acquisition Event, and (iii) with respect to any such Person who becomes a Subsidiary, (A) such Subsidiary is the only obligor in respect of such Indebtedness, and (B) to the extent such Indebtedness is permitted to be secured by Collateral Agent and Lenders in their discretion, only the assets of such Subsidiary secure such Indebtedness;

(l) Indebtedness consisting of earn outs, obligations with respect to purchase price adjustments, and other deferred payments of similar nature arising under agreements entered into in connection with Acquisition Event;

(m) Other unsecured Indebtedness not to exceed Five Hundred Thousand Dollars (\$500,000.00) in the aggregate at any time;

(n) Parent guaranties of real estate leases and capital leases of another Borrower; and

(o) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (n) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be.

**“Permitted Investments” are:**

(a) Investments disclosed on the Perfection Certificate(s) and existing on the Effective Date;

(b) (i) Investments consisting of cash and Cash Equivalents, and (ii) any other Investments permitted by Borrower’s investment policy, as amended from time to time, provided that such investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent (and Collateral Agent acknowledges the investment policy delivered on or prior to the Effective Date is hereby approved);

(c) Investments consisting of the endorsement of negotiable instruments for deposit or collection or similar transactions in the ordinary course of Borrower;

(d) Investments consisting of deposit and securities accounts in which Collateral Agent has a perfected security interest (other than Excluded Accounts to the extent not required under Section 6.6) which Investments are in accordance with the Borrower’s investment policy (and any such amendment thereto) has been approved in writing by Collateral Agent;

(e) Investments in connection with Transfers permitted by Section 7.1;

(f) Investments (i) by Borrower or any Subsidiary in Subsidiaries that are not Loan Parties not to exceed One Million Dollars (\$1,000,000.00) in the aggregate in any fiscal year; and (ii) by Borrower or any Subsidiary in or to any Loan Party;

(g) Investments consisting of (i) travel advances and employee relocation loans and other employee loans and advances in the ordinary course of business, and (ii) loans to employees, officers or directors relating to the purchase of equity securities of Borrower or its Subsidiaries pursuant to employee stock purchase plans or agreements approved by Borrower’s Board of Directors; not to exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate for (i) and (ii) in any fiscal year;

(h) Investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business;

(i) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (i) shall not apply to Investments of Borrower in any Subsidiary;

(j) non-cash Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business consisting of the non-exclusive licensing of technology and Intellectual Property, the development of technology and Intellectual Property or the providing of technical support;

(k) Investments constituting interest rate, currency or commodity swap agreement, interest rate cap agreement, interest rate collar agreement, or other agreement or arrangement designated to protect Borrower or a Subsidiary against fluctuation in interest rates, currency exchange rates or commodity prices; provided, that the aggregate amount of Investments allowed under this clause (k) shall not exceed One Hundred Thousand Dollars (\$100,000.00) in any given fiscal year;

(l) Investments in joint ventures or strategic alliances in the ordinary course of Borrower's business, provided that any cash Investments by Borrower do not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) in the aggregate in any fiscal year;

(m) Acquisition Event;

(n) Investments acquired after the date of this Agreement in connection with Acquisition Event, to the extent that such Investments were not made in contemplation of such acquisition, merger, amalgamation or consolidation and were in existence on the date of such acquisition, merger, amalgamation or consolidation; and

(o) other Investments not otherwise permitted herein provided that the aggregate amount of all such Investments in any year shall not exceed Five Hundred Thousand Dollars (\$500,000.00).

**"Permitted Licenses"** are (A) licenses of over-the-counter software that is commercially available to the public, and (B) non-exclusive and exclusive licenses for the use of the Intellectual Property of Borrower or any of its Subsidiaries entered into in the ordinary course of business, provided, that, with respect to each such license described in clause (B), (i) no Event of Default has occurred or is continuing at the time of such license; (ii) the license constitutes an arms-length transaction, the terms of which, on their face, do not provide for a sale or assignment of any Intellectual Property and do not restrict the ability of Borrower or any of its Subsidiaries, as applicable, to pledge, grant a security interest in or lien on, or assign or otherwise Transfer any Intellectual Property; (iii) in the case of any exclusive license, (x) Borrower delivers ten (10) days' prior written notice and a brief summary of the terms of the proposed license to Collateral Agent and the Lenders and delivers to Collateral Agent and the Lenders copies of the final executed licensing documents in connection with the exclusive license promptly upon consummation thereof, and (y) any such license could not result in a legal transfer of title of the licensed property but may be exclusive in respects other than territory and may be exclusive as to territory only as to discrete geographical areas outside of the United States; and (iv) all upfront payments, royalties, milestone payments or other proceeds arising from the licensing agreement that are payable to Borrower or any of its Subsidiaries are paid to a Deposit Account that is governed by a Control Agreement.

**"Permitted Liens"** are:

(a) Liens existing on the Effective Date and disclosed on the Perfection Certificates or arising under this Agreement and the other Loan Documents;

(b) Liens for taxes, fees, assessments or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on its Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code of 1986, as amended, and the Treasury Regulations adopted thereunder;

(c) Liens securing Indebtedness permitted under clause (e) of the definition of **"Permitted Indebtedness,"** provided that (i) such Liens exist prior to the acquisition of, or attach substantially simultaneous

with, or within ninety (90) days after the, acquisition, lease, repair, improvement or construction of, such property financed or leased by such Indebtedness and (ii) such Liens do not extend to any property of Borrower other than the property (and proceeds thereof) acquired, leased or built, or the improvements or repairs, financed by such Indebtedness;

(d) Liens of carriers, warehousemen, suppliers, or other Persons that are possessory in nature arising in the ordinary course of business so long as such Liens attach only to Inventory, securing liabilities in the aggregate amount not to exceed One Hundred Thousand Dollars (\$100,000.00), and which are not delinquent or remain payable without penalty or which are being contested in good faith and by appropriate proceedings which proceedings have the effect of preventing the forfeiture or sale of the property subject thereto;

(e) Liens to secure payment of workers' compensation, employment insurance, old-age pensions, social security and other like obligations incurred in the ordinary course of business (other than Liens imposed by ERISA);

(f) leases or subleases of real property granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), and leases, subleases, non-exclusive licenses or sublicenses of personal property (other than Intellectual Property) granted in the ordinary course of Borrower's business (or, if referring to another Person, in the ordinary course of such Person's business), if the leases, subleases, licenses and sublicenses do not prohibit granting Collateral Agent or any Lender a security interest therein;

(g) banker's liens, rights of setoff and Liens in favor of financial institutions incurred in the ordinary course of business arising in connection with Borrower's deposit accounts or securities accounts held at such institutions solely to secure payment of fees and similar costs and expenses and provided such accounts are maintained in compliance with Section 6.6(b) hereof;

(h) Liens arising from judgments, decrees or attachments in circumstances not constituting an Event of Default under Section 8.4 or 8.7;

(i) Liens consisting of Permitted Licenses;

(j) Liens consisting of deposits made in the ordinary course of Borrower's or a Subsidiary's business, securing liabilities to secure the performance of tenders, statutory obligations, surety, bid and appeal bonds, bids, leases, government contracts, trade contracts, performance and return-of-money bonds and other similar obligations; provided, however, the aggregate amount of such deposits at any given time may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00);

(k) easements, reservations, rights-of-way, restrictions, minor defects or irregularities in title and other similar Liens affecting real property not interfering in any material respect with the ordinary course of the business of Borrower;

(l) Liens or deposits to secure the performance of leases incurred in the ordinary course of business and not representing an obligation for borrowed money and Liens to secure tenant improvements, provided the lessor thereof has executed a landlord consent in favor of, and in form and content reasonably acceptable to Collateral Agent if required pursuant to Section 7.2; provided, however, the sum of the aggregate amount of the Indebtedness secured by such Liens and the aggregate amount of such deposits at any given time may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00); and

(m) Liens in favor of customs and revenue authorities arising as a matter of law, in the ordinary course of Borrower's business, to secure payment of customs duties in connection with the importation of

goods; provided, however, the aggregate amount of Indebtedness secured by such Liens may not exceed Two Hundred Fifty Thousand Dollars (\$250,000.00) at any given time.

“**Person**” is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

“**Prepayment Fee**” is, with respect to any Term Loan subject to prepayment prior to the Maturity Date, whether by mandatory or voluntary prepayment, acceleration or otherwise, an additional fee payable to the Lenders in amount equal to:

(i) for a prepayment made on or after the Funding Date of such Term Loan through and including the first anniversary of the Funding Date of such Term Loan, three percent (3.00%) of the principal amount of such Term Loan prepaid;

(ii) for a prepayment made after the date which is after the first anniversary of the Funding Date of such Term Loan through and including the second anniversary of the Funding Date of such Term Loan, two percent (2.00%) of the principal amount of the Term Loans prepaid; and

(iii) for a prepayment made after the date which is after the second anniversary of the Funding Date of such Term Loan and prior to the Maturity Date, one percent (1.00%) of the principal amount of the Term Loans prepaid.

“**Pro Rata Share**” is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of Term Loans held by such Lender by the aggregate outstanding principal amount of all Term Loans.

“**Registered Organization**” is any “registered organization” as defined in the Code with such additions to such term as may hereafter be made.

“**Required Lenders**” means (i) for so long as all of the Persons that are Lenders on the Effective Date (each an “**Original Lender**”) have not assigned or transferred any of their interests in their Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after any Original Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least sixty six percent (66%) of the aggregate outstanding principal balance of the Term Loan and, in respect of this clause (ii), (A) each Original Lender that has not assigned or transferred any portion of its Term Loan, (B) each assignee or transferee of an Original Lender’s interest in the Term Loan, but only to the extent that such assignee or transferee is an Affiliate or Approved Fund of such Original Lender, and (C) any Person providing financing to any Person described in clauses (A) and (B) above; provided, however, that this clause (C) shall only apply upon the occurrence of a default, event of default or similar occurrence with respect to such financing.

“**Requirement of Law**” is as to any Person, the organizational or governing documents of such Person, and any law (statutory or common), treaty, rule or regulation or determination of an arbitrator or a court or other Governmental Authority, in each case applicable to or binding upon such Person or any of its property or to which such Person or any of its property is subject.

“**Responsible Officer**” is any of the President and Chief Executive Officer, or Chief Financial Officer of Borrower acting alone.

“**Second Draw Period**” is the period commencing on the earliest date by which both the Acquisition Event shall have occurred and the entire amount of Term A Loans shall have been funded hereunder, and ending on the earlier of (i) March 31, 2019 and (ii) the occurrence of an Event of Default; provided, however, that the Second

Draw Period shall not commence if on the date of the occurrence of the Acquisition Event an Event of Default has occurred and is continuing.

“**Secured Promissory Note**” is defined in Section 2.4.

“**Secured Promissory Note Record**” is a record maintained by each Lender with respect to the outstanding Obligations owed by Borrower to Lender and credits made thereto.

“**Securities Account**” is any “securities account” as defined in the Code with such additions to such term as may hereafter be made.

“**Shares**” is one hundred percent (100%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or Borrower’s Subsidiary, in any Subsidiary; provided that, in the event Borrower, demonstrates to Collateral Agent’s reasonable satisfaction, that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary which is a Foreign Subsidiary, creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code, “Shares” shall mean sixty-five percent (65%) of the issued and outstanding capital stock, membership units or other securities owned or held of record by Borrower or its Subsidiary in such Foreign Subsidiary.

“**Solvent**” is, with respect to any Person: the fair salable value of such Person’s consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person’s liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature.

“**Subordinated Debt**” is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance reasonably satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms reasonably acceptable to Collateral Agent and the Lenders.

“**Subsidiary**” is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries (other than any joint venture or strategic alliances).

“**Term Loan**” is defined in Section 2.2(a)(ii) hereof.

“**Term A Loan**” is defined in Section 2.2(a)(i) hereof.

“**Term B Loan**” is defined in Section 2.2(a)(ii) hereof.

“**Term Loan Commitment**” is, for any Lender, the obligation of such Lender to make a Term Loan, up to the principal amount shown on Schedule 1.1. “**Term Loan Commitments**” means the aggregate amount of such commitments of all Lenders.

“**Trademarks**” means any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of Borrower or the applicable Subsidiary connected with and symbolized by such trademarks.

“**Transfer**” is defined in Section 7.1.

“**UK Share Pledge**” is a share pledge agreement, under the laws of England and Wales, with respect to the Shares of the UK Subsidiary, in such form and substance as are satisfactory to Collateral Agent and Lenders

“**UK Subsidiary**” is Aclaris Therapeutics International Limited, a private limited company existing under the laws of England and Wales.

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**BORROWER:**

ACLARIS THERAPEUTICS, INC.

By /s/ Neal Walker  
Name: Neal Walker  
Title: President & Chief Executive Officer

CONFLUENCE DISCOVERY TECHNOLOGIES, INC.

By /s/ Neal Walker  
Name: Neal Walker  
Title: President & Chief Executive Officer

ACLARIS LIFE SCIENCES, INC.

By /s/ Neal Walker  
Name: Neal Walker  
Title: President

**COLLATERAL AGENT AND LENDER:**

OXFORD FINANCE LLC

By /s/ Colette H. Featherly  
Name: Colette H. Featherly  
Title: Senior Vice President

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SCHEDULE 1.1

Lenders and Commitments

**Term A Loans**

<b>Lender</b>	<b>Term A Loan Commitment</b>	<b>Commitment Percentage</b>
OXFORD FINANCE LLC	\$30,000,000.00	100.00%
<b>TOTAL</b>	<b>\$30,000,000.00</b>	<b>100.00%</b>

**Term B Loans**

<b>Lender</b>	<b>Term B Loan Commitment</b>	<b>Commitment Percentage</b>
OXFORD FINANCE LLC	\$35,000,000.00	100.00%
<b>TOTAL</b>	<b>\$35,000,000.00</b>	<b>100.00%</b>

**Aggregate (all Term Loans)**

<b>Lender</b>	<b>Term Loan Commitment</b>	<b>Commitment Percentage</b>
OXFORD FINANCE LLC	\$65,000,000.00	100.00%
<b>TOTAL</b>	<b>\$65,000,000.00</b>	<b>100.00%</b>

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## EXHIBIT A

### Description of Collateral

The Collateral consists of all of Borrower's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) more than sixty five percent (65%) of the Shares of a Foreign Subsidiary, if Borrower demonstrates to Collateral Agent's reasonable satisfaction that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code; (iii) Excluded Accounts, and (iv) any license, contract or interest of Borrower as a lessee under a lease, in each case if the granting of a Lien in such license, contract or interest is prohibited by or would constitute a default under the agreement governing such license, contract or interest (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Section 9-406, 9-408 or 9-409 (or any other Section) or Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license, contract or interest, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral".

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Borrower has agreed not to encumber any of its Intellectual Property.

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**EXHIBIT B**

**Form of Disbursement Letter**

[see attached]

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## DISBURSEMENT LETTER

[DATE]

The undersigned, being the duly elected and acting \_\_\_\_\_ of ACLARIS THERAPEUTICS, INC., a Delaware corporation ("**Parent**") with offices located at 640 Lee Road, Suite 200, Wayne, PA 19087, CONFLUENCE DISCOVERY TECHNOLOGIES, INC., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 ("**CDT**") and ACLARIS LIFE SCIENCES, INC., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 ("**ALS**") (Parent, CDT and ALS, individually and collectively, jointly and severally, "**Borrower**"), does hereby certify to **OXFORD FINANCE LLC** ("**Oxford**" and "**Lender**"), as collateral agent (the "**Collateral Agent**") in connection with that certain Loan and Security Agreement dated as of October 15, 2018, by and among Borrower, Collateral Agent and the Lenders from time to time party thereto (the "**Loan Agreement**"; with other capitalized terms used below having the meanings ascribed thereto in the Loan Agreement) that:

1. The representations and warranties made by Borrower in Section 5 of the Loan Agreement and in the other Loan Documents are true and correct in all material respects as of the date hereof; provided, that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date.
2. No event or condition has occurred that would constitute an Event of Default under the Loan Agreement or any other Loan Document.
3. Borrower is in compliance with the covenants and requirements contained in Sections 4, 6 and 7 of the Loan Agreement.
4. All conditions referred to in Section 3 of the Loan Agreement to the making of the Loan to be made on or about the date hereof have been satisfied or waived by Collateral Agent.
5. No Material Adverse Change has occurred.
6. The undersigned is a Responsible Officer.

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7. The proceeds of the Term [A][B] Loan shall be disbursed as follows:

**Disbursement from Oxford:**

Loan Amount	\$ _____
Plus:	
—Deposit Received	\$ _____
Less:	
—Facility Fee	(\$ _____)
[—Interim Interest	(\$ _____)]
—Lender’s Legal Fees	(\$ _____)*

**Net Proceeds due from Oxford:** \$ \_\_\_\_\_

**TOTAL TERM LOAN NET PROCEEDS FROM LENDERS** \$ \_\_\_\_\_

8. The Term [A][B] Loan shall amortize in accordance with the Amortization Table attached hereto.

9. The aggregate net proceeds of the Term [A][B] Loans shall be transferred to the Designated Deposit Account as follows:

Account Name: [ACLARIS THERAPEUTICS, INC.]  
Bank Name: [\_\_\_\_\_]   
Bank Address: [\_\_\_\_\_]   
Account Number: \_\_\_\_\_   
ABA Number: [\_\_\_\_\_]

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\* Legal fees and costs are through the Effective Date. Post-closing legal fees and costs, payable after the Effective Date, to be invoiced and paid post-closing.

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Dated as of the date first set forth above.

**BORROWER:**

ACLARIS THERAPEUTICS, INC.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

CONFLUENCE DISCOVERY TECHNOLOGIES, INC.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

ACLARIS LIFE SCIENCES, INC.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

**COLLATERAL AGENT AND LENDER:**

OXFORD FINANCE LLC

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**AMORTIZATION TABLE**  
(Term [A][B] Loan)

[see attached]

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EXHIBIT C

Compliance Certificate

TO: OXFORD FINANCE LLC, as Collateral Agent and Lender

FROM: ACLARIS THERAPEUTICS, INC., on behalf of itself and all Borrowers

The undersigned authorized officer (“Officer”) of ACLARIS THERAPEUTICS, INC., on behalf of itself and all Borrowers hereby certifies that in accordance with the terms and conditions of the Loan and Security Agreement by and among Borrower, Collateral Agent, and the Lenders from time to time party thereto (the “Loan Agreement;” capitalized terms used but not otherwise defined herein shall have the meanings given them in the Loan Agreement),

(a) Borrower is in complete compliance for the period ending \_\_\_\_\_ with all required covenants except as noted below;

(b) There are no Events of Default, except as noted below;

(c) Except as noted below, all representations and warranties of Borrower stated in the Loan Documents are true and correct in all material respects on this date and for the period described in (a), above; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date.

(d) Borrower, and each of Borrower’s Subsidiaries, has timely filed all required tax returns and reports, Borrower, and each of Borrower’s Subsidiaries, has timely paid all foreign, federal, state, and material local taxes, assessments, deposits and contributions (i.e. local taxes, assessments, deposits and contributions in an aggregate amount of \$50,000 or more) owed by Borrower, or Subsidiary, except as otherwise permitted pursuant to the terms of Section 5.8 of the Loan Agreement;

(e) No Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Collateral Agent and the Lenders.

Attached are the required documents, if any, supporting our certification(s). The Officer, on behalf of Borrower, further certifies that the attached financial statements are prepared in accordance with Generally Accepted Accounting Principles (GAAP) and are consistently applied from one period to the next except as explained in an accompanying letter or footnotes and except, in the case of unaudited financial statements, for the absence of footnotes and subject to year-end audit adjustments as to the interim financial statements, which unaudited financial statements are considered to be in draft form and subject to adjustment in accordance with Section 5.4 of the Loan Agreement.

Please indicate compliance status since the last Compliance Certificate by circling Yes, No, or N/A under “Complies” column.

	Reporting Covenant	Requirement	Actual	Complies		
1)	Financial statements	Monthly within 30 days		Yes	No	N/A

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2)	Annual (CPA Audited) statements	Within 120 days after FYE	Yes	No	N/A
3)	Annual Financial Projections/Budget (prepared on a monthly basis)	Annually (within 60 days of FYE), and when revised	Yes	No	N/A
4)	A/R & A/P agings	If applicable	Yes	No	N/A
5)	8-K, 10-K and 10-Q Filings	If applicable, within 5 Business Days of filing	Yes	No	N/A
6)	Compliance Certificate	Monthly within 30 days	Yes	No	N/A
7)	IP Report of material adverse changes	When required	Yes	No	N/A
8)	Total amount of Borrower's cash and cash equivalents at the last day of the measurement period	\$ _____	Yes	No	N/A
9)	Total amount of Borrower's Subsidiaries' cash and cash equivalents at the last day of the measurement period	\$ _____	Yes	No	N/A
10)	[***] product revenues	\$ _____	Yes	No	N/A

**Deposit and Securities Accounts**

*(Please list all accounts; attach separate sheet if additional space needed)*

	Institution Name	Account Number	New Account?		Account Control Agreement in place?	
1)			Yes	No	Yes	No
2)			Yes	No	Yes	No
3)			Yes	No	Yes	No
4)			Yes	No	Yes	No

**Financial Covenants**

	Covenant	Requirement	Actual	Compliance	
1)	[***] product revenues	[\$ _____]	[\$ _____]	Yes	No

**Other Matters**

- |    |  |     |    |
|----|--|-----|----|
| 1) | Have there been any changes in management since the last Compliance Certificate?                               | Yes | No |
| 2) | Have there been any transfers/sales/disposals/retirement of Collateral or IP prohibited by the Loan Agreement? | Yes | No |

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- |    |  |     |    |
|----|--|-----|----|
| 3) | Have there been any new or pending claims or causes of action against Borrower that involve more than Five Hundred Thousand Dollars (\$500,000.00)?  | Yes | No |
| 4) | Have there been any amendments of or other changes to the capitalization table of Borrower and to the Operating Documents of Borrower or any of its Subsidiaries? If yes, provide copies of any such amendments or changes with this Compliance Certificate. | Yes | No |

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**Exceptions**

Please explain any exceptions with respect to the certification above: (If no exceptions exist, state "No exceptions." Attach separate sheet if additional space needed.)

ACLARIS THERAPEUTICS, INC., on behalf of itself and all Borrowers

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

Date:

**LENDER USE ONLY**

Received by: \_\_\_\_\_ Date: \_\_\_\_\_  
Verified by: \_\_\_\_\_ Date: \_\_\_\_\_

Compliance Status: Yes No

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**EXHIBIT D**

**Form of Secured Promissory Note**

[see attached]

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**SECURED PROMISSORY NOTE**  
**(Term [A][B] Loan)**

\$ \_\_\_\_\_

Dated: [DATE]

FOR VALUE RECEIVED, the undersigned, ACLARIS THERAPEUTICS, INC., a Delaware corporation (“**Parent**”) with offices located at 640 Lee Road, Suite 200, Wayne, PA 19087, CONFLUENCE DISCOVERY TECHNOLOGIES, INC., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 (“**CDT**”) and ACLARIS LIFE SCIENCES, INC., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 (“**ALS**”) (Parent, CDT and ALS, individually and collectively, jointly and severally, “**Borrower**”) HEREBY PROMISES TO PAY to the order of OXFORD FINANCE LLC (“**Lender**”) the principal amount of [\_\_\_\_\_] MILLION DOLLARS (\$\_\_\_\_\_) or such lesser amount as shall equal the outstanding principal balance of the Term [A][B] Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term [A][B] Loan, at the rates and in accordance with the terms of the Loan and Security Agreement dated October 15, 2018 by and among Borrower, Lender, Oxford Finance LLC, as Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the “**Loan Agreement**”). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term [A][B] Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this “**Note**”). The principal amount of this Note and the interest rate applicable thereto, and all payments made with respect thereto, shall be recorded by Lender and, prior to any transfer hereof, endorsed on the grid attached hereto which is part of this Note.

The Loan Agreement, among other things, (a) provides for the making of a secured Term [A][B] Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term [A][B] Loan, interest on the Term [A][B] Loan and all other amounts due Lender under the Loan Agreement is secured under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys’ fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower’s obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the State of New York.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of

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this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

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IN WITNESS WHEREOF, Borrower has caused this Note to be duly executed by one of its officers thereunto duly authorized on the date hereof.

**BORROWER:**

ACLARIS THERAPEUTICS, INC.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

CONFLUENCE DISCOVERY TECHNOLOGIES, INC.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

ACLARIS LIFE SCIENCES, INC.

By \_\_\_\_\_  
Name: \_\_\_\_\_  
Title: \_\_\_\_\_

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**LOAN INTEREST RATE AND PAYMENTS OF PRINCIPAL**

<b>Date</b>	<b>Principal Amount</b>	<b>Interest Rate</b>	<b>Scheduled Payment Amount</b>	<b>Notation By</b>
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**CORPORATE BORROWING CERTIFICATE**

**BORROWER:** [BORROWER]  
**LENDER:** OXFORD FINANCE LLC, as Collateral Agent and Lender

**DATE:** [DATE]

I hereby certify as follows, as of the date set forth above:

1. I am the Secretary, Assistant Secretary or other officer of Borrower. My title is as set forth below.
2. Borrower's exact legal name is set forth above. Borrower is a [BORROWER ORGANIZATION] existing under the laws of the State of [BORROWER STATE].
3. Attached hereto as Exhibit A and Exhibit B, respectively, are true, correct and complete copies of (i) Borrower's Articles/Certificate of Incorporation (including amendments), as filed with the Secretary of State of the state in which Borrower is incorporated as set forth in paragraph 2 above; and (ii) Borrower's Bylaws. Neither such Articles/Certificate of Incorporation nor such Bylaws have been amended, annulled, rescinded, revoked or supplemented, and such Articles/Certificate of Incorporation and such Bylaws remain in full force and effect as of the date hereof.
4. The following resolutions were duly and validly adopted by Borrower's Board of Directors at a duly held meeting of such directors (or pursuant to a unanimous written consent or other authorized corporate action). Such resolutions are in full force and effect as of the date hereof and have not been in any way modified, repealed, rescinded, amended or revoked, and the Lenders may rely on them until each Lender receives written notice of revocation from Borrower.

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<u>Name</u>	<u>Title</u>	<u>Signature</u>	Authorized to Add or Remove <u>Signatories</u>
_____	_____	_____	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>
_____	_____	_____	<input type="checkbox"/>

**RESOLVED FURTHER**, that **any one** of the persons designated above with a checked box beside his or her name may, from time to time, add or remove any individuals to and from the above list of persons authorized to act on behalf of Borrower.

**RESOLVED FURTHER**, that such individuals may, on behalf of Borrower:

**Borrow Money.** Borrow money from the Lenders.

**Execute Loan Documents.** Execute any loan documents any Lender requires.

**Grant Security.** Grant Collateral Agent a security interest in any of Borrower's assets.

**Negotiate Items.** Negotiate or discount all drafts, trade acceptances, promissory notes, or other indebtedness in which Borrower has an interest and receive cash or otherwise use the proceeds.

**Further Acts.** Designate other individuals to request advances, pay fees and costs and execute other documents or agreements (including documents or agreement that waive Borrower's right to a jury trial) they believe to be necessary to effectuate such resolutions.

**RESOLVED FURTHER**, that all acts authorized by the above resolutions and any prior acts relating thereto are ratified.

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5. The persons listed above are Borrower's officers or employees with their titles and signatures shown next to their names.

**By:** \_\_\_\_\_  
**Name:** \_\_\_\_\_  
**Title:** \_\_\_\_\_

\*\*\* If the Secretary, Assistant Secretary or other certifying officer executing above is designated by the resolutions set forth in paragraph 4 as one of the authorized signing officers, this Certificate must also be signed by a second authorized officer or director of Borrower.

I, the \_\_\_\_\_ of Borrower, hereby certify as to paragraphs 1 through 5 above, as  
[print title]  
of the date set forth above.

**By:** \_\_\_\_\_  
**Name:** \_\_\_\_\_  
**Title:** \_\_\_\_\_

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**EXHIBIT A**

**Articles/Certificate of Incorporation (including amendments)**

[see attached]

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**EXHIBIT B**

**Bylaws**

[see attached]

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**DEBTOR:** [BORROWER]  
**SECURED PARTY:** OXFORD FINANCE LLC,  
as Collateral Agent

**EXHIBIT A TO UCC FINANCING STATEMENT**

**Description of Collateral**

The Collateral consists of all of Debtor's right, title and interest in and to the following personal property:

All goods, Accounts (including health-care receivables), Equipment, Inventory, contract rights or rights to payment of money, leases, license agreements, franchise agreements, General Intangibles (except as noted below), commercial tort claims, documents, instruments (including any promissory notes), chattel paper (whether tangible or electronic), cash, deposit accounts and other Collateral Accounts, all certificates of deposit, fixtures, letters of credit rights (whether or not the letter of credit is evidenced by a writing), securities, and all other investment property, supporting obligations, and financial assets, whether now owned or hereafter acquired, wherever located; and

All Borrower's Books relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any Intellectual Property; provided, however, the Collateral shall include all Accounts and all proceeds of Intellectual Property. If a judicial authority (including a U.S. Bankruptcy Court) would hold that a security interest in the underlying Intellectual Property is necessary to have a security interest in such Accounts and such property that are proceeds of Intellectual Property, then the Collateral shall automatically, and effective as of the Effective Date, include the Intellectual Property to the extent necessary to permit perfection of Collateral Agent's security interest in such Accounts and such other property of Borrower that are proceeds of the Intellectual Property; (ii) more than sixty five percent (65%) of the Shares of a Foreign Subsidiary, if Borrower demonstrates to Collateral Agent's reasonable satisfaction that a pledge of more than sixty five percent (65%) of the Shares of such Subsidiary creates a present and existing adverse tax consequence to Borrower under the U.S. Internal Revenue Code; (iii) Excluded Accounts, and (iv) any license, contract or interest of Borrower as a lessee under a lease, in each case if the granting of a Lien in such license, contract or interest is prohibited by or would constitute a default under the agreement governing such license, contract or interest (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Section 9-406, 9-408 or 9-409 (or any other Section) or Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license, contract or interest, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral".

Pursuant to the terms of a certain negative pledge arrangement with Collateral Agent and the Lenders, Debtor has agreed not to encumber any of its Intellectual Property.

Capitalized terms used but not defined herein have the meanings ascribed in the Uniform Commercial Code in effect in the State of New York as in effect from time to time (the "Code") or, if not defined in the Code, then in the Loan and Security Agreement by and between Debtor, Secured Party and the other Lenders party thereto (as modified, amended and/or restated from time to time).

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## FIRST AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIRST AMENDMENT to Loan and Security Agreement (this "**Amendment**") is entered into as of January 28, 2019 (the "**Amendment Date**"), by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 ("**Oxford**"), as collateral agent (in such capacity, "**Collateral Agent**"), the Lenders listed on Schedule 1.1 to the Loan Agreement (as defined below) or otherwise a party thereto from time to time including Oxford in its capacity as a Lender (each a "**Lender**" and collectively, the "**Lenders**"), and ACLARIS THERAPEUTICS, INC., a Delaware corporation ("**Parent**") with offices located at 640 Lee Road, Suite 200, Wayne, PA 19087, Confluence Discovery Technologies, Inc., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 ("**CDT**") and ACLARIS LIFE SCIENCES, INC., a Delaware corporation with offices located at 4320 Forest Park Avenue, Suite 303, St. Louis, MO 63108 ("**ALS**") (Parent, CDT and ALS, individually and collectively, jointly and severally, "**Borrower**").

WHEREAS, Collateral Agent, Borrower and Lenders have entered into that certain Loan and Security Agreement, dated as of October 15, 2018 (as amended, supplemented or otherwise modified from time to time, the "**Loan Agreement**") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

WHEREAS, Borrower, Lenders and Collateral Agent desire to amend certain provisions of the Loan Agreement and the Disbursement Letters entered into pursuant to the Loan Agreement as provided herein and subject to the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Lenders and Collateral Agent hereby agree as follows:

1. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.
2. Section 13.1 of the Loan Agreement is hereby amended by amending and restating the following definition therein as follows:

"**Excluded Accounts**" means any (i) Deposit Accounts exclusively used for payroll, payroll taxes and other employee wage and benefit payments to or for the benefit of Borrower's or its Subsidiaries employees, (ii) escrow accounts in which funds have been deposited by Borrower (and are yet to be released) to meet its obligations related to an acquisition by Borrower which has been consented to by Collateral Agent and Required Lenders, (iii) LC Account and (iv) Collateral Accounts of any Subsidiary that is not a Loan Party.

3. Section 13.1 of the Loan Agreement is hereby further amended by adding the following definition thereto in alphabetical order:

"**LC Account**" means an account maintained by Borrower exclusively for the purposes of securing Indebtedness permitted under clause (i) of the definition of "Permitted Indebtedness" and identified by Borrower to Collateral Agent as such in the Perfection Certificate(s); provided, however, the aggregate balance in such account may not exceed at any time the amount of Indebtedness then outstanding that is permitted under clause (i) of the definition of "Permitted Indebtedness."

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4. Section 13.1 of the Loan Agreement is hereby further amended by amending and restating clause (i) of the definition of "Permitted Indebtedness" therein as follows:

(i) Indebtedness in respect of letters of credit, bank guarantees and similar instruments issued for the account of the Borrower or any Subsidiary in the ordinary course of business supporting obligations under (A) workers' compensation, unemployment insurance and other social security laws and (B) bids, trade contracts, leases, statutory obligations, surety and appeal bonds, performance bonds and obligations of a like nature; provided the aggregate amount of Indebtedness under this clause (i) may not exceed One Million Four Hundred Thousand Dollars (\$1,500,000.00) at any given time;

5. Section 13.1 of the Loan Agreement is hereby further amended by amending the definition of "Permitted Liens" by removing "and" at the end of clause (l) thereof, replacing "." at the end of clause (m) thereof with "; and" and adding the following clause (n) thereto:

(n) Liens on LC Account securing Indebtedness permitted under clause (i) of the definition of "Permitted Indebtedness."

6. Limitation of Amendment.

a. The amendments set forth above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, are hereby ratified and confirmed and shall remain in full force and effect.

7. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

c. The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by or on behalf of the Borrower to the Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect;

d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual

restriction with a Person binding on Borrower, (iii) any material order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

- e. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and
  - f. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.
8. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.
  9. The Borrower hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent ("**Releasees**"), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any act, omission or state of facts taken or existing on or prior to the date hereof, may have after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof and through the date hereof. Without limiting the generality of the foregoing, the Borrower waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan Documents; (b) any provision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof.
  10. This Amendment shall be deemed effective as of the Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto and (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited (or ACH'd) from the Designated Deposit Account in accordance with Section 2.3(d) of the Loan Agreement.
  11. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.
  12. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of New York.

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**IN WITNESS WHEREOF**, the parties hereto have caused this First Amendment to the Loan Agreement to be executed as of the date first set forth above.

**BORROWER:**

ACLARIS THERAPEUTICS, INC.

By /s/ Neal Walker  
Name: Neal Walker  
Title: President & CEO

CONFLUENCE DISCOVERY TECHNOLOGIES, INC.

By /s/ Neal Walker  
Name: Neal Walker  
Title: President & CEO

ACLARIS LIFE SCIENCES, INC.

By /s/ Neal Walker  
Name: Neal Walker  
Title: President

**COLLATERAL AGENT AND LENDER:**

OXFORD FINANCE LLC

By /s/ Colette H. Featherly  
Name: Colette H. Featherly  
Title: Senior Vice President

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## Subsidiaries of Aclaris Therapeutics, Inc.

Name of Subsidiary	Jurisdiction of Incorporation or Organization
Aclaris Therapeutics International Limited	United Kingdom
Aclaris Life Sciences, Inc.	Delaware
Confluence Discovery Technologies, Inc.	Delaware

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**CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM**

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (No. 333-212095) and Form S-8 (Nos. 333-223922, 333-220149, 333-216703, 333-210379, and 333-307434) of Aclaris Therapeutics, Inc. of our report dated March 18, 2019 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania  
March 18, 2019

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Neal Walker, certify that:

1. I have reviewed this annual report on Form 10-K of Aclaris Therapeutics, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 18, 2019

/s/ Neal Walker  
\_\_\_\_\_  
Neal Walker  
President & Chief Executive Officer  
(principal executive officer)

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**CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER  
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Frank Ruffo, certify that:

1. I have reviewed this annual report on Form 10-K of Aclaris Therapeutics, Inc. (the “registrant”);
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant’s other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - (c) Evaluated the effectiveness of the registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - (d) Disclosed in this report any change in the registrant’s internal control over financial reporting that occurred during the registrant’s most recent fiscal quarter (the registrant’s fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant’s internal control over financial reporting; and
5. The registrant’s other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
  - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
  - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: March 18, 2019

/s/ Frank Ruffo

Frank Ruffo  
Chief Financial Officer  
(principal financial officer and principal accounting officer)

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**CERTIFICATIONS OF  
PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER  
PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), Neal Walker, President and Chief Executive Officer of Aclaris Therapeutics, Inc. (the "Company"), and Frank Ruffo, Chief Financial Officer of the Company, each hereby certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the period ended December 31, 2018 (the "Annual Report"), to which this Certification is attached as Exhibit 32.1, fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and
2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition of the Company as of the end of the period covered by the Annual Report and results of operations of the Company for the periods covered by the Annual Report.

**In Witness Whereof**, the undersigned have set their hands hereto as of the 18th day of March, 2019.

/s/ Neal Walker  
\_\_\_\_\_  
Neal Walker  
President & Chief Executive Officer

/s/ Frank Ruffo  
\_\_\_\_\_  
Frank Ruffo  
Chief Financial Officer

\* This certification accompanies the Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

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