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

FORM 10-K

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF
THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2019 **Commission file number 001-37581**

ACLARIS THERAPEUTICS, INC.

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

640 Lee Road, Suite 200
Wayne, PA 19087
(484) 324-7933

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

Title of Each Class:	Trading Symbol(s)	Name of Each Exchange on which Registered
Common Stock, $0.00001 par value	ACRS	The Nasdaq Stock Market, LLC

Securities registered pursuant to Section 12(g) of the 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 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 28, 2019, 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 $79.6 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 February 24, 2020, 41,528,822 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 2020 Annual Meeting of Stockholders are incorporated by reference in Part III of this Form 10-K.

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 develop our drug candidates;
- the timing of our planned clinical trials of our drug candidates and the reporting of the results from these trials;
- the clinical utility of our drug candidates;
- our plans and expectations related to manufacturing capabilities and strategy;
- our expectations regarding coverage and reimbursement of our drug candidates, if approved;
- the timing of our regulatory filings and approvals for our drug candidates;
- our intellectual property position;
- our plans to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates and our FDA-approved product, ESKATA, and earn revenue from such arrangements;
- our expectations regarding competition;
- our expectations regarding our continued reliance on third parties;
- 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, RHOFADE, KINect 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

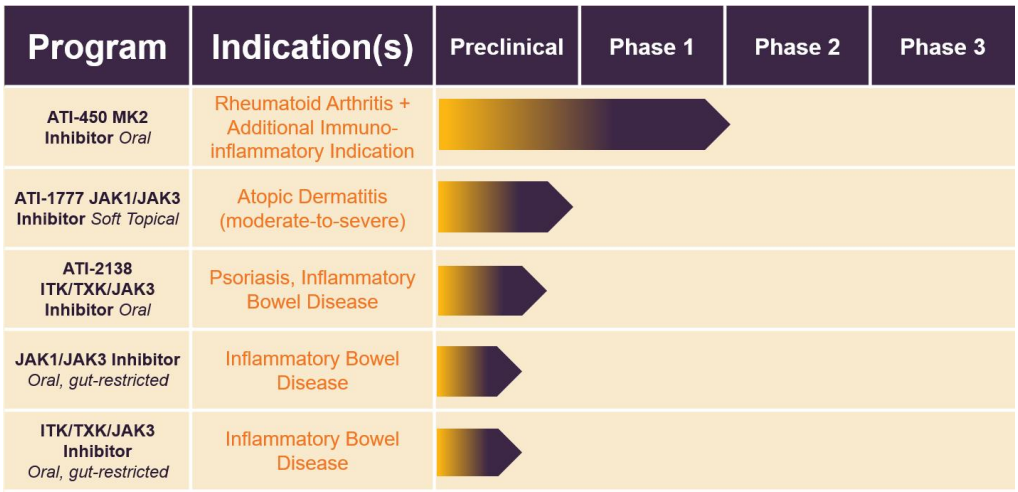
Item 1. Business

Overview

We are a physician-led biopharmaceutical company focused on immuno-inflammatory diseases. We currently have a pipeline of drug candidates focused on immuno-inflammatory diseases, as well as one product approved by the U.S. Food and Drug Administration, or FDA, that we are not currently distributing, marketing or selling, and other investigational drug candidates. In September 2019, we announced the completion of a strategic review of our business, as a result of which we are refocusing our resources on our immuno-inflammatory development programs. We plan to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates and ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, our non-marketed FDA-approved product.

Our Drug Candidates Currently in Development

Our pipeline of drug candidates that we are currently developing is summarized in the table below:



MK2 Inhibitors, JAK Inhibitors and ITK Inhibitors as Potential Treatments for Immuno-Inflammatory Diseases

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 also earn revenue from Confluence's provision of contract research services to third parties. We intend to leverage our proprietary drug discovery platform acquired from Confluence, called KINect, to identify potential drug candidates that we may develop independently or in collaboration with third parties. We also acquired several preclinical drug candidates, including inhibitors of the mitogen-activated protein kinase-activated protein kinase 2, or MK2, signaling pathway, topical Janus kinase, or JAK, inhibitors known as soft-JAK inhibitors, and inhibitors of interleukin-2-inducible T cell kinase, or ITK.

We submitted an Investigational New Drug Application, or IND, in April 2019 for ATI-450, an investigational oral, novel, small molecule selective MK2 inhibitor compound, for the treatment of rheumatoid arthritis, which was allowed by the FDA in May 2019. MK2 is a key regulator of pro-inflammatory mediators including TNFα, IL1β, IL6, IL8 and other essential pathogenic signals in chronic immuno-inflammatory diseases, as well as in cancer. As an oral drug candidate, we are developing ATI-450 as a potential alternative to injectable anti-TNF/IL1/IL6 biologics for treating

certain immuno-inflammatory diseases. We initiated a Phase 1 single and multiple ascending dose clinical trial in 77 healthy subjects in August 2019. Preliminary data from this trial demonstrated that ATI-450 resulted in marked inhibition of TNFα, IL1β, IL8 and IL6. We also observed that ATI-450 had dose-proportional pharmacokinetics with a terminal half-life of 9-12 hours in the multiple ascending dose cohort, and had no meaningful food effect or drug-drug interaction with methotrexate. ATI-450 was generally well-tolerated at all doses tested in the trial. The most common adverse events (reported by 2 or more subjects who received ATI-450) observed during the trial were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain, and nausea. Based on the results of the Phase 1 trial, we intend to initiate a Phase 2a clinical trial for ATI-450 in subjects with rheumatoid arthritis in the first half of 2020. We are also planning to initiate a Phase 2a clinical trial of ATI-450 for an additional immuno-inflammatory indication.

We expect to submit an IND for ATI-1777, an investigational topical soft-JAK inhibitor compound, for the treatment of atopic dermatitis in mid-2020. Soft-JAK inhibitors are designed to be topically applied and active in the skin, but rapidly metabolized and inactivated when they enter the bloodstream, which may result in low systemic exposure. If the IND is allowed, we expect to initiate a Phase 1/2 clinical trial in healthy subjects and subjects with atopic dermatitis in the second half of 2020 evaluating ATI-1777 as a potential treatment for moderate-to-severe atopic dermatitis.

We are also developing ATI-2138, our investigational oral ITK/TXK/JAK3, or ITJ, inhibitor compound, as a potential treatment for psoriasis and/or inflammatory bowel disease, which are both T-cell mediated autoimmune diseases. The ITJ compound interrupts T cell signaling through the combined inhibition of ITK/TXK/JAK3 pathways in lymphocytes. We expect to file an IND for ATI-2138 in the fourth quarter of 2020 or the first quarter of 2021.

Our Other Drug Candidates and FDA-Approved Product

A-101 45% Topical Solution as a Potential Treatment for Common Warts

We are developing a high-concentration formulation of hydrogen peroxide, A-101 45% Topical Solution, as a potential prescription treatment for common warts, also known as verruca vulgaris. 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. Cryosurgery is the most frequently used in-office treatment for common warts. Common warts can also be treated with over-the-counter products, such as those containing salicylic acid. We are not aware of any prescription drugs that have been approved by the FDA for the treatment of common warts.

In September 2018, we commenced two pivotal Phase 3 clinical trials, which we refer to as THWART-1 and THWART-2, evaluating a twice-weekly dosing regimen of A-101 45% Topical Solution for the treatment of common warts. In each of the THWART-1 trial and THWART-2 trial, which we completed in October 2019 and September 2019, respectively, subjects treated with A-101 45% Topical Solution achieved clinically meaningful and statistically significant outcomes for the primary and secondary efficacy endpoints. No treatment-related serious adverse events were observed in the trials. The most common adverse events occurring in more than 5% of subjects in the A-101 45% Topical Solution group were adverse events at the application site such as pain, scabbing, erythema, pruritus, pallor and erosion.

In February 2019, we commenced an open-label safety extension trial investigating A-101 45% Topical Solution as a potential treatment for common warts.

We are pursuing strategic alternatives, including seeking a partner, to obtain regulatory approval and commercialize A-101 45% Topical Solution as a potential treatment for common warts.

ATI-501 and ATI-502 as a Potential Treatment for Alopecia

In 2015, we in-licensed exclusive, worldwide rights from Rigel Pharmaceuticals, Inc., or Rigel, to certain inhibitors of the JAK family of enzymes, which we refer to as ATI-501 and ATI-502, an oral and topical formulation, respectively, for specified dermatological conditions, including alopecia areata, or AA, androgenetic alopecia, or AGA, also known as male or female pattern baldness, vitiligo and atopic dermatitis. We are pursuing strategic alternatives, including seeking a partner, to further develop, obtain regulatory approval and commercialize ATI-501 and ATI-502 as potential treatments for alopecia.

ESKATA for the Treatment of Raised Seborrheic Keratosis

ESKATA, our only FDA-approved product, is a proprietary formulation of high-concentration hydrogen peroxide topical solution which was approved by the 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. In August 2019, we voluntarily discontinued the commercialization of ESKATA in the United States, but we continue to maintain the New Drug Application, or NDA, for ESKATA in the United States. We also withdrew the marketing authorizations we had previously received for the product in all countries outside of the United States. We are pursuing strategic alternatives, including seeking a strategic partner, to commercialize ESKATA.

Our Commercial Product Which We Have Divested

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

In November 2018, we acquired RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, which included an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan Sales, LLC, or Allergan. In October 2019, we sold the worldwide rights to RHOFADE, which included the assignment of certain licenses for related intellectual property assets, to EPI Health, LLC, or EPI Health, as described further below under "—Acquisitions and License Agreements."

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 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 is used in A-101 45% Topical Solution for the potential treatment of common warts and ESKATA for the treatment of raised SKs. 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 may assign the agreement without the consent of PeroxyChem in connection with the sale, transfer or license of the products covered by the agreement.

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 A-101 45% Topical Solution and 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 may assign the agreement without the consent of James Alexander in connection with the sale of the products to which the agreement relates.

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 drug candidates, if approved, will compete with existing treatments and new treatments that may become available in the future.

With respect to A-101 45% Topical Solution for the treatment of common warts, we are aware of the following companies that are developing a drug candidate for the treatment of common warts: Nielsen BioSciences, Inc. and Verrica Pharmaceuticals Inc. In addition, there are over-the-counter drugs for the treatment of common warts and other drugs that have been used off-label as treatments for common warts.

With respect to ATI-450 as a potential treatment for rheumatoid arthritis, there are numerous commercial products, such as anti-TNFs, anti-IL6s, anti-IL1s and JAK inhibitors, approved for the treatment of rheumatoid arthritis. In addition, we are aware of a number of companies conducting late-stage clinical trials for investigational drug candidates for the treatment of rheumatoid arthritis.

The commercial opportunity for our drug candidates, if approved, 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 any drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drug candidates more rapidly than our potential third-party partners may obtain approval for our drug candidates, which could result in our competitors establishing a strong market position before our drug candidates 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, and preclinical and clinical development 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 development programs.

Intellectual Property

Our success depends in large part upon our ability to obtain and maintain proprietary protection for our drug candidates and to operate without infringing the proprietary rights of others. We seek to avoid the latter by monitoring patents and publications that may affect our business, and to the extent we identify such developments, evaluate and take appropriate courses of action. Our policy is to protect our proprietary position by, among other methods, filing 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 our inhibitors of the MK2 signaling pathway, we own two U.S. patents and pending applications in the European Union and other foreign countries that cover ATI-450, our lead candidate, and certain methods of use. The U.S. patents expire 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 numerous U.S. patents and pending foreign patent applications directed to other inhibitors of the MK2 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, including ATI-1777, 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, including pending U.S. and PCT applications to ATI-2138, and methods of using the same. The patents and pending applications, if issued, expire between 2035 and 2039, subject to any applicable patent term adjustment or extension that may be available in a particular country.

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 two issued U.S. patents, one issued patent in Australia and pending applications in Canada, the European Union and Japan with claims that cover the use of these compounds for the treatment of AA. The U.S. and Australian patents, 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 expire in 2031. We also exclusively license patents 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, which expire in 2031. In addition, we exclusively license a patent application in the United States directed to 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 A-101 45% Topical Solution and ESKATA, we do not currently rely on licenses to any third party's intellectual property. We own two U.S. patents that include claims that cover the use of high-concentration hydrogen peroxide of at least 23%, including A-101 45% Topical Solution and ESKATA, for the alleviation of SK and acrochordons. The patents in Australia, New Zealand and India include claims that cover the use of high-concentration hydrogen peroxide of at least 23%, including A-101 45% Topical Solution and ESKATA, for the alleviation of various skin conditions including SK, acrochordons, corns, tags, acne, warts and rosacea. The patents in Germany, the United Kingdom, Mexico and Singapore include claims that cover the use of high-concentration hydrogen peroxide of at least 23%, including A-101 45% Topical Solution and ESKATA, for the alleviation of acrochordons. The issued patents relating to the use of A-101 45% Topical Solution and ESKATA begin to expire in 2022, subject to any applicable patent term extension that may be available in a particular country.

We also own four issued U.S. patents and pending U.S., European and other foreign patent applications directed to various formulations comprising high-concentration hydrogen peroxide, including A-101 45% Topical Solution and ESKATA, 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.

We also use other forms of protection, such as trademark, copyright, and trade secret protection, to protect our intellectual property, particularly where we do not believe patent protection is appropriate or obtainable. We aim to take advantage of all of the intellectual property rights that are available to us and believe that this comprehensive approach will provide us with proprietary positions for our drug candidates, where available.

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

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

Acquisition and License Agreements

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 remaining contingent consideration of up to $75.0 million, based upon the achievement of specified regulatory and commercial milestones set forth in the Confluence Agreement. In addition, we have agreed to pay the former Confluence equity holders 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.

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, which we amended in October 2019. Under this agreement, we may develop these JAK inhibitors for the treatment of AA and other dermatological conditions. We are required to use commercially reasonable efforts to develop, seek regulatory approval and commercialize at least one product, which is deemed satisfied by us using commercially reasonable efforts to find a third party to use commercially reasonable efforts to develop, seek regulatory approval and commercialize at least one product. We paid Rigel an upfront nonrefundable payment of $8.0 million and $4.0 million upon the achievement of a specified development milestone, and have agreed to make remaining aggregate payments of up to $76.0 million upon the achievement of specified development milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional $10.5 million to Rigel upon the achievement of a second set of development milestones. In addition, in connection with the amendment of the agreement in October 2019, we agreed to pay Rigel an amendment fee of $1.5 million in three installments of $0.5 million in January 2020, April 2020 and July 2020. 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 and at least one product for the treatment of AGA, 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 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. With respect to any covered products that we commercialize under 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.

Asset Purchase Agreement with EPI Health

In October 2019, we entered into an Asset Purchase Agreement, or APA, with EPI Health, pursuant to which we sold the worldwide rights to RHOFADE, which included the assignment of certain licenses for related intellectual property assets, or the Disposition.

Pursuant to the APA, EPI Health paid us an upfront payment of $35.0 million ($1.75 million of which was placed in escrow) and $200,000 for inventory. In addition, EPI Health has agreed to pay us (i) potential sales milestone payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales (as defined in the APA) of products covered by the APA, (ii) a specified high single-digit royalty calculated as a percentage of net sales, on a product-by-product and country-by-country basis, until the date that the patent rights related to a particular product, such as RHOFADE, have expired, provided, that with respect to sales of RHOFADE in any territory outside of the United States, such royalty shall be paid on a country-by-country basis until the date that the RHOFADE patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADE in such country and (iii) 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the Disposition in any territory outside of the United States, subject to specified exceptions. In addition, EPI Health has agreed to assume our obligation to pay specified royalties and milestone payments under our existing agreements with Allergan, Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc.

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 A-101 45% Topical Solution and ESKATA. 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 A-101 45% Topical Solution and ESKATA 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 $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 and 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.

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 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. 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 that any third-party partners that we may consummate a transaction with would seek approval through the NDA pathway. A-101 45% Topical Solution is comprised of both a drug component (the hydrogen peroxide solution) and a pen-type applicator. Based on our discussions with the FDA to date, we do not anticipate that the FDA will require the submission of 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. However, physicians may, in their independent medical judgment, prescribe legally available products for off-label uses. The FDA does not regulate the behavior of physicians in their choice of treatments but the FDA does restrict manufacturer's communications on the subject of off-label use of their products.

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 drug candidates. 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

Even if we obtain FDA approval for a drug candidate, 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 our potential third-party partners must obtain approval of the regulators of such countries or economic areas, such as the European Union, before they may market any of our drug candidates 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 any of our drug candidates for which marketing approval is obtained. Our potential third-party partners' arrangements with third-party payors, health care professionals and customers may expose them 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 they sell, market and distribute any drug candidates for which marketing approval is obtained. In addition, we and our potential third-party partners 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 or they conduct 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 monetary 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, activities relating to the sale and marketing of 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 a product is sold in a foreign country, the seller 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, as defined by such law, 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.

We have developed a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we are 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, imprisonment, 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.

There remain judicial and Congressional challenges to, as well as efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act. For example, since January 2017, President Trump has signed two executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, two bills affecting the implementation of certain taxes under the Affordable Care Act have been signed into law. The Tax Cuts and Jobs Act of 2017 includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the Affordable Care Act on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate". In addition, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. 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 December 2018, the Centers for Medicare & Medicaid Services, or CMS, published a new 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. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, 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 2029, 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 2020 contains further drug price control measures that could be enacted during the 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 solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS' policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization 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 believe the success of our drug candidates, if approved, will depend on obtaining and maintaining coverage and adequate reimbursement as 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 our potential third-party partners may not be able to negotiate or continue to negotiate reimbursement or pricing terms for our drug candidates, if approved, 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 our drug candidates, if approved. Our drug candidates, if approved, 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 our potential third-party partners to sell our drug candidates, if approved, 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 our potential third-party partners could receive for any of our drug candidates, if approved, 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 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 drug candidates, if approved, 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 drug candidate to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be

harmed if reimbursement of our drug candidates, if approved, is unavailable or limited in scope or amount or if pricing is set at unsatisfactory levels.

Employees

As of December 31, 2019, we had 77 total employees, of which 75 were full-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. Our common stock is listed on the Nasdaq Global Select Market under the symbol “ACRS.”

Available Information

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

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the Securities and Exchange Commission, or SEC. The SEC also maintains a website that contains our reports, proxy and information statements and other information. The address of the SEC’s website is www.sec.gov.

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 $161.4 million and $132.7 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of $453.5 million. We have financed our operations over the last several years primarily from public offerings and a private placement of our common stock, as well as debt financing that has since been repaid in full. We have one commercial product, ESKATA, that we are no longer distributing, marketing or selling, one late-stage investigational drug candidate and other preclinical and clinical drug candidates that we are developing.

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 from 2018 to October 2019, 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 in the near term as we:

- pursue strategic alternatives, including identifying and seeking to consummate transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates and ESKATA;
- continue the clinical development of ATI-450, our MK2 inhibitor, as a potential treatment for rheumatoid arthritis and potentially an additional immuno-inflammatory indication;
- continue to develop our preclinical drug candidates, including ATI-1777, a soft-JAK inhibitor, and ATI-2138, an ITJ inhibitor;
- seek to discover and develop additional drug candidates;
- maintain, expand and protect our intellectual property portfolio; and
- incur legal, accounting, investor relations and other administrative expenses in operating as a public company.

To become and remain profitable, we must succeed in a range of challenging activities, including completing preclinical testing and clinical trials of our drug candidates and pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, for the further development and/or commercialization of our drug candidates, as well as discovering and developing additional drug candidates. We are in the early stages of most of these activities. We may never succeed in these activities and, even if we do, may never earn revenue from our drug candidates that is significant enough to achieve profitability.

For any of our drug candidates, our revenue will be dependent, in part, upon our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize those drug candidates. Further, we will be dependent on our potential third-party partners' ability to obtain marketing approval and successfully commercialize the product, upon the size of the markets in the territories where marketing approval is obtained, the accepted price for the product, and the ability to obtain coverage and reimbursement, if any. If we fail to identify and enter into partnerships with third parties to further develop, obtain marketing approval for and/or commercialize our drug candidates, any partnerships we enter into do not result in the successful development, marketing approval for and commercialization of our drug candidates, the number of addressable patients is not as significant as estimated by our potential third-party partners, the indication approved by regulatory authorities is narrower than expected, or the treatment population is narrowed by competition, physician choice or treatment guidelines, we may not earn significant revenue from agreements with potential third-party partners for such drug candidates, even if the drug candidates are approved for marketing.

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, the development of any of our drug candidates or the identification and consummation of transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize 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, 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.

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 identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical and clinical development. In addition, we may not be able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and our drug candidates, if approved, may not achieve commercial success. 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 of December 31, 2019, we had cash, cash equivalents and marketable securities of $75.0 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 number and development requirements of the drug candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our drug candidates;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the extent to which we in-license or acquire additional drug candidates and technologies;
- 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;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and earn revenue from such arrangements; and
- the revenue earned from our commercial products as a result of licenses to, or partnerships with, third parties.

We expect that we will require additional capital to complete the clinical development of ATI-450, to develop our preclinical compounds and to support our discovery efforts. 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.

Our business is dependent on the successful development of our drug candidate, ATI-450.

Our pipeline includes ATI-450, our investigational oral, novel, selective MK2 inhibitor compound, which we are developing for rheumatoid arthritis and potentially for an additional immuno-inflammatory indication. We expect to initiate a Phase 2a clinical trial for ATI-450 in subjects with rheumatoid arthritis in the first half of 2020. The success of our business will significantly depend on our successful development of and/or our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize ATI-450.

Raising additional capital may cause dilution to our stockholders, restrict our operations or require us to relinquish rights to our technologies, intellectual property, potential future revenue streams or drug candidates.

Until such time, if ever, as we can earn substantial revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings and license and partnership 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 partnerships, strategic alliances or marketing, distribution or licensing arrangements with third-party partners, we may be required to relinquish valuable rights to our technologies, intellectual property, potential future revenue streams, or drug candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings or other arrangements with third parties when needed, we may be required to delay, limit, reduce or terminate our drug development efforts or grant rights to third parties to develop technologies, intellectual property, or drug candidates that we would otherwise prefer to develop ourselves.

We have a limited operating history and recently changed our strategic focus to focus on the development of our immuno-inflammatory portfolio, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

Our operations over the last several years have been largely focused on raising capital, undertaking preclinical studies and conducting clinical trials, and acquiring new drug candidates and related intellectual property. In 2018 and 2019, we were also focused on the commercialization of two commercial products. In September 2019, we announced the completion of a strategic review of our business, as a result of which we are refocusing our resources on our immuno-inflammatory development programs and are pursuing strategic alternatives, including seeking partners, for our investigational drug candidates and ESKATA. We have had limited time to demonstrate our ability to successfully develop, manufacture and identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. 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 developing and partnering drugs. We may also encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

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 obtaining marketing approval for our drug candidates 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 by a potential third-party partner could be delayed.

Risks Related to the Development and Potential Commercialization of Our Drug Candidates

If we are unable to successfully develop our drug candidates and to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or 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 earn substantial revenue from our drug candidates will depend heavily on our ability to successfully develop and pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize these drug candidates. The success of any drug candidates that we develop, including A-101 45% Topical Solution and ATI-450, will depend on several factors, including:

- successful completion of preclinical studies and our clinical trials;
- successful development of manufacturing processes for any of our drug candidates that receive marketing approval;
- receipt of timely approvals from applicable regulatory authorities;
- the identification and consummation of transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates;
- the commercial launch of our drug candidates by a third-party partner, if approved;
- our third-party partners' ability to achieve 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 third-party partners' ability to achieve 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 the intellectual property portfolio;
- maintaining compliance with regulatory requirements, including current good manufacturing practices, or cGMPs;
- our third-party partners' ability to compete effectively with other treatment procedures; and
- our third-party partners' ability to maintain a continued acceptable safety, tolerability and efficacy profile of our drug candidates following marketing 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, the 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 additional studies or clinical trials, additional data, or additional manufacturing steps, or require other conditions before they will reconsider or approve the application. If the FDA or other comparable foreign regulatory authorities require additional studies, clinical trials or data, this could increase costs and cause delays in the marketing approval process, which may require the expenditure of additional resources. These delays would also impact our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates. 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. 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 pursue strategic alternatives, including identifying and consummating transactions with third-party

partners, to further develop, obtain marketing approval for and/or 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 of and pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize 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 pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/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, our costs will increase, our drug candidate development process will be slowed, the commercial prospects of our drug candidates

will be harmed, and our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates will be delayed. 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 not be able to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates, and our potential third-party partners 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. 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 our potential third-party partners may have the exclusive right to commercialize our drug candidates or allow competitors to bring drugs to market before such third-party partners do, which would impact our ability to successfully identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

If we experience delays or difficulties in the enrollment of subjects in clinical trials, our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates 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. Any delays in completing clinical trials would delay or prevent our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates.

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 our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates, increase our costs or necessitate the abandonment or limitation of the development of some of our drug candidates.

Before any potential third-party partners can obtain 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;
- a medication guide outlining the risks of such side effects for distribution to patients may be required;
- we could be sued and held liable for harm caused to patients;
- our reputation and physician or patient acceptance of our drug candidates, if approved, may suffer; and
- our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates would be harmed.

Any of these events could prevent us from pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize 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 pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates.

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

A key element of our strategy is to build and expand our pipeline of drug candidates. To build our pipeline, we may seek to in-license or acquire additional drug candidates. 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 ATI-450 as a potential treatment for rheumatoid arthritis and an additional immuno-inflammatory indication. 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 partnerships, 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.

For any of our drug candidates that receive marketing approval, our third-party partners 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.

For any of our drug candidates that receive marketing approval, our third-party partners may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our third-party partners fail to obtain an adequate level of acceptance for our drug candidates, we may not earn significant revenue and we may not become profitable. The degree of market acceptance of any drug candidate, if approved, will depend on a number of factors, including:

- the efficacy, safety and potential advantages compared to alternative treatments;
- our third-party partners' ability to offer the 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;
- the ability of our potential third-party partners to retain a sales force;
- the strength of our potential third-party partners' marketing and distribution support;
- the availability of third-party payor coverage and adequate reimbursement or the willingness of patients to pay for these products;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

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 will face competition with respect to any drug candidates that we may seek to develop or through our potential third-party partners, commercialize, in the future, from many different sources, including major pharmaceutical, biotechnology and specialty pharmaceutical companies, academic institutions and governmental agencies and public and private research institutions.

With respect to A-101 45% Topical Solution for the treatment of common warts, we are aware of at least two other companies that are developing a drug candidate for the treatment of common warts. In addition, there are over-the-counter drugs for the treatment of common warts and other drugs that have been used off-label as treatments for common warts.

With respect to ATI-450 as a potential treatment for rheumatoid arthritis, there are numerous commercial products, such as anti-TNFs, anti-IL6s, anti-IL1s and JAK inhibitors, approved for the treatment of rheumatoid arthritis. In addition, we are aware of a number of companies conducting late-stage clinical trials for investigational drug candidates for the treatment of rheumatoid arthritis.

The commercial opportunity for our drug candidates, if approved, could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than a drug that we may develop. Our competitors also may obtain FDA or other regulatory approval for their drugs more rapidly than our third-party partners' may obtain approval for our drug candidates, which could result in our competitors establishing a strong market position before our drug candidates 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, and preclinical and clinical development 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 development programs.

The success of our drug candidates, if approved, will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these products.

We believe the success of our drug candidates, if approved, will depend on obtaining and maintaining coverage and adequate reimbursement as 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 our potential third-party partners 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 our drug candidates, if approved. Our drug candidates, if approved, 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 our potential third-party partners to sell our drug candidates, if approved, on a competitive and profitable basis. Our results of operations could be adversely affected by the Affordable Care Act and by other health care legislative 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 our potential third-party partners could receive for any of our drug candidates, if approved, 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 drug candidates could harm our business.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to our drug candidates, if approved, 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 drug candidate to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our drug candidates, if approved, 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 drug candidates that we may develop and are commercialized by our potential third-party partners or impact any commercial products that we have previously sold or are being sold by third-party partners.

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 any of our commercial products that we have previously sold or are being sold by third-party partners. If we cannot successfully defend ourselves against claims that our commercial products that we have previously sold or are being sold by third-party partners or drug candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any drug candidates that we may develop and are commercialized by our potential third-party partners;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and
- our inability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates.

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 rely on third parties to conduct clinical trials for our 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 identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or 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 earn revenue from those partnerships 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, European Medicines Agency or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving 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 for our potential third-party partners.

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

We contract with third parties for the manufacture and 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 our drug candidates or such quantities at an acceptable cost, which could delay, prevent or impair our development efforts.

We do not have any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture 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 is used in A-101 45% Topical Solution for the potential treatment of common warts. This reliance on third parties increases the risk that we will not have sufficient quantities of our drug candidates at an acceptable cost and/or quality, which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development efforts.

The facilities used by our contract manufacturers to manufacture our drug candidates must be approved by the FDA or other regulatory authorities pursuant to inspections that will be conducted after the NDA or comparable marketing application is submitted to the FDA or other regulatory authority. We do not have control over a supplier's or manufacturer's compliance with laws, regulations and applicable cGMP standards and other laws and regulations, such as those related to environmental health and safety matters. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, they will not be able to secure and maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our drug candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which could significantly impact our ability to develop, and identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize, 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 for our drug candidates; 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 drug candidates.

Our drug candidates 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 of our drug candidates.

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 do not currently have arrangements in place for redundant supply or a second source for the active pharmaceutical ingredients and/or drug product for our drug candidates.

We expect to continue to depend on third-party contract manufacturers for the foreseeable future. Our current and anticipated future dependence upon others for the manufacture of our drug candidates may adversely affect our future profit margins and our ability to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates on a timely and competitive basis.

We intend to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates. If those arrangements are not successful, we may not be able to capitalize on the market potential of these drug candidates.

We intend to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates. For example, we intend to seek a partner to obtain marketing approval and commercialize A-101 45% Topical Solution as a potential treatment for common warts and a partner to further develop, obtain marketing approval and commercialize ATI-501 and ATI-502 as potential treatments for alopecia. Our likely partners for any such 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 partners dedicate to the development or commercialization of our drug candidates. Our ability to earn revenue from these arrangements will depend on our partners' abilities to successfully perform the functions assigned to them in these arrangements.

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

- partners have significant discretion in determining the efforts and resources that they will apply to these arrangements;
- partners may not perform their obligations as expected;
- partners may not pursue development, marketing approval or 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 partners' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- partners 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;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our drug candidates if the partners 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 our partners to cease to devote resources to the development and/or commercialization of our drug candidates, if approved;
- a partner 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 partners, including disagreements over proprietary rights, contract interpretation or the preferred course of development or commercialization, 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;
- partners 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;
- partners may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- partnerships may be terminated for the convenience of the partner and, if terminated, we could be required to raise additional capital to pursue further development and/or commercialization of the applicable drug candidates.

Partnership agreements may not lead to development, marketing approval or commercialization of drug candidates in the most efficient manner or at all. If a present or future partner 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 partnerships, we may have to alter our development and commercialization plans.

Our drug development programs for our drug candidates will require substantial additional capital. For some of our drug candidates, we intend to partner with pharmaceutical and biotechnology companies for the further development and/or commercialization of those drug candidates.

We face significant competition in seeking appropriate partners. Whether we reach a definitive agreement for a partnership will depend, among other things, upon our assessment of the partner's resources and expertise, the terms and conditions of the proposed arrangement and the proposed partner'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 partner may also consider alternative drug candidates or technologies for similar indications that may be available to partner on and whether such a partnership could be more attractive than the one with us for our drug candidate. Partnerships 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 partners.

We may not be able to negotiate partnerships 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, or reduce or delay its development program or one or more of our other development programs, 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.

We may not have access to all information regarding our drug candidates that are subject to partnership agreements. Consequently, our ability to inform our stockholders about the status of our drug candidates that are subject to these agreements, and our ability to make business and operational decisions, may be limited.

We may not have access to all information regarding our drug candidates that may become subject to agreements with partners, including potentially material information about clinical trial design, execution and timing, safety and efficacy, clinical trial results, regulatory affairs, manufacturing, marketing, sales and other areas known by our potential partners. In addition, we may have confidentiality obligations under our agreements with such partners. Therefore, our ability to keep our stockholders informed about the status of our drug candidates will be limited by the degree to which our partners keep us informed and by the degree to which our partners allow us to disclose information to the public or

provide such information to the public themselves. If our partners do not timely inform us about the status of our drug candidates that are the subject of the partnership, we may make operational and investment decisions that we would not have made had we been fully informed, which may have an adverse impact on our business, prospects, financial condition and results of operations.

We are dependent upon EPI Health for the commercialization of RHOFADE, and if we successfully pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop and/or commercialize our drug candidates and ESKATA, we will be dependent on the success of such third-party partners.

In October 2019, we sold the worldwide rights to RHOFADE to EPI Health. Among other payment obligations, EPI Health has agreed to pay us potential sales milestone payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales, a specified high single-digit royalty calculated as a percentage of net sales, and 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in any territory outside of the United States, subject to specified exceptions. We also intend to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain regulatory approval and/or commercialize our drug candidates and ESKATA. We cannot control the timing or quantity of resources that our existing or future potential third-party partners will dedicate to developing and/or commercializing these products and drug candidates. Our partners may not perform their obligations according to our expectations or standards of quality. Our partners could terminate our existing agreements for a number of reasons, including that they may have other, higher priority products in development or because our partnered programs may no longer be a priority for them. If any of our partnership agreements were to be terminated or if any of our partners do not perform as expected, we could lose the opportunity to earn any revenues from the arrangements with such third-party partners, incur unforeseen costs, and suffer damage to the reputation of the product and as a company generally.

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 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 ability to successfully identify a potential third-party partner to commercialize our technology and drug candidates may be impaired.

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

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

The patent position of biotechnology and pharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation. In addition, the laws of foreign countries may not protect our rights to the same extent as the laws of the United States or vice versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than 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 drug candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drug candidates. 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 drug candidates and compete directly with us, without payment to us, or result in the inability of our potential third-party partners to manufacture or commercialize our drug candidates 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 partnering with us to license, develop and/or commercialize our 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 our potential third-party partners or otherwise provide us or our potential third-party partners with any competitive advantage. 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 have issued and may issue with claims directed to the use of specific JAK inhibitors that we do not intend to develop or 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 the ability to stop others from using or commercializing similar or identical technology and drug candidates, or limit the duration of the patent protection of our technology and drug candidates. Our issued U.S. patents covering our lead inhibitor of the MK2 signaling pathway, ATI-450, expire in 2034 and other issued patents covering different MK2 signaling pathway inhibitors expire in 2031 and 2032. We currently do not have any patents issued directed to our lead soft-JAK inhibitor, ATI-1777, but any claims that may issue would expire in 2038. We currently do not have any patents issued directed to our lead ITK inhibitor, ATI-2138, but any claims that may issue would expire in 2039. Our issued patents covering other novel inhibitors of ITK expire between 2035 and 2038. 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., European, Japanese and South Korean 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. 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, are scheduled to expire in 2022, and our issued U.S. patents with claims directed to high-concentration hydrogen peroxide formulations, including A-101 45% Topical Solution and ESKATA, and methods of use and applicators for the same are scheduled to expire in 2035. 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 or our potential third-party partners with sufficient rights to exclude others from commercializing drugs similar or identical to ours.

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

Competitors may infringe our issued patents or other intellectual property. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from

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

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

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.

If we breach our license agreement with Rigel, it could compromise our ability to identify and consummate transactions with potential third-party partners to further develop, obtain marketing approval for and commercialize our JAK inhibitors, ATI-501 and ATI-502.

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 or failure to use commercially reasonable efforts to find a third party 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, which would negatively impact our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize ATI-501 and ATI-502.

If we breach our agreement with the Selling Stockholders of Vixen, it could compromise our ability to identify and consummate transactions with potential third-party partners to further develop, obtain marketing approval for and commercialize our JAK inhibitors, ATI-501 and ATI-502.

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 alopecia, 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, which would negatively impact our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize ATI-501 and ATI-502.

If we breach our agreement with Columbia University, it could compromise our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize our JAK inhibitors, ATI-501 and ATI-502.

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 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, which would negatively impact our ability to find a potential third-party partner to develop, obtain marketing approval for and commercialize ATI-501 and ATI-502.

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

Filing, prosecuting and defending patents on our drug candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. For example, the use of A-101 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. An additional four U.S. patents are 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/or A-101 45% Topical Solution and methods of use.

Our lead inhibitor of the MK2 signaling pathway, ATI-450, is currently covered in patents and applications in the United States, European Union and other major foreign markets. We currently do not have any patents issued directed to our lead soft-JAK inhibitor, ATI-1777, or our lead ITK inhibitor, ATI-2138. 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., European, Japanese, and South Korean 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 and South Korea.

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 ability to pursue strategic alternatives, including identifying and consummating transactions with potential third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates, and consequently 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 and/or commercialization of our drug candidates. For example, 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 our potential third-party partners to use the patented or proprietary technology of third parties to further develop and/or commercialize our drug candidates. If our potential third-party partners are not able to obtain a license from these third parties on commercially reasonable terms, 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 our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize those drug candidates for dermatological indications, which in turn would impact our ability to earn revenue from the arrangements with such third-party partners. 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 JAK inhibitor drug candidates, if they are 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 success depends upon our ability to pursue strategic alternatives, including identifying and consummating transactions with potential third-party partners, to develop, obtain marketing approval for and/or commercialize our drug candidates and earn revenue from those partnerships, and for our proprietary technologies to be used 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 drug candidates and technologies, 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 or our potential third-party partners are found to infringe a third party's intellectual property rights, we or such partners could be required to obtain a license from such third party to continue developing or commercializing our drug candidates and technology. However, we or our third-party partners may not be able to obtain any required license on commercially reasonable terms or at all. Even if we or our third-party partner were able to obtain a license, it could be non-exclusive, thereby giving competitors access to the same technologies licensed to us or our partner. Consequently, we or our third-party partner could be forced, including by court order, to cease developing or commercializing the infringing technology or drug candidate. In addition, we or our third-party partner could be found liable for monetary damages, including treble damages and attorneys' fees if we or such partner are found to have willfully infringed a patent. A finding of infringement could prevent our third-party partners from commercializing our drug candidates, if approved, or force such partners to cease some of their business operations. In the event of a successful claim of infringement against us or our potential third-party partners, we or our third-party partners may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing drug candidate 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. 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 compete in the marketplace, including compromising our ability to raise the funds necessary to continue our clinical trials, continue our internal research programs, or pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or 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 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 any of our commercial products or any of our drug candidates can be challenged by competitors.

The likelihood that a third party will challenge the patents covering a commercial product is increased because it is a marketed product. 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 a commercial product, 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 our commercial products.

On October 8, 2019, we, together with Allergan, Inc., filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Taro Pharmaceuticals, Inc., or Taro, related to an ANDA that Taro filed with the FDA to market a generic version of RHOFADE. The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for RHOFADE. We received a Paragraph IV Notice Letter from Taro dated August 28, 2019, advising that Taro had submitted an ANDA to the FDA seeking approval from the FDA to manufacture and market a generic version of RHOFADE prior to the expiration of the Orange Book-listed patents. EPI Health, as purchaser of our rights to RHOFADE, has been substituted for us as a plaintiff party. If EPI Health is not able to successfully defend the RHOFADE intellectual property and a generic version of RHOFADE is approved, our ability to earn revenue from EPI Health through the achievement of sales milestones, licensing in jurisdictions outside of the United States and/or royalty payments would be negatively impacted.

If any of our drug candidates advance through development or are 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 drug candidates, our business may be materially harmed.

Our success will largely depend on our ability to obtain and maintain patent and other intellectual property in the United States and other countries with respect to our proprietary technology, drug candidates and our target indications. Our issued U.S. patents covering ATI-450, our lead inhibitor of the MK2 signaling pathway, expire in 2034 and other issued patents covering different MK2 signaling pathway inhibitors expire in 2031 and 2032. We currently do not have any patents issued directed to our lead soft-JAK inhibitor, ATI-1777, but any claims that may issue would expire in 2038. We currently do not have any patents issued directed to our lead ITK inhibitor, ATI-2138, but any claims that may issue would expire in 2039. Our issued patents covering other novel inhibitors of ITK expire between 2035 and 2038. 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., European, Japanese and South Korean patents licensed from Columbia University relating to the use of certain third-party JAK inhibitors for the treatment of hair loss disorders, including AA and AGA, and inducing hair growth, expire in 2031. 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 and applicator patents with claims directed to high-concentration hydrogen peroxide formulations and applicators containing the same, including A-101 45% Topical Solution and ESKATA, and methods of use is scheduled to expire in 2035. 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 Drug Price Competition and Patent Term Restoration Act of 1984, or 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.

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.

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 our products, services or technologies from those 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, our products, services or technologies may need to be rebranded, which could result in loss of brand recognition and could require us to devote resources to advertising and marketing new brands. Our competitors may infringe our trademarks and we may not have adequate resources to enforce our trademarks.

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

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

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

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

- others may be able to make formulations or compositions that are the same as or similar to A-101 45% Topical Solution and ESKATA 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 partner that is not covered by the patents that we exclusively license and have the right to enforce;
- we, our licensors or any third-party partners 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 third-party partners 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 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 our potential third-party partners are not able to obtain, or if there are delays in obtaining, required regulatory approvals, our drug candidates will not be able to be commercialized, and our ability to earn revenue from arrangements with such third-party partners 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 our potential third-party partners from commercializing the drug candidate. 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 potential third-party partners from 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 product in this way, which could limit sales of the product.

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 our potential third-party partners ultimately obtain may be limited or subject to restrictions or post-approval commitments that render the approved drug not commercially viable.

If our potential third-party partners experience delays in obtaining approval or if they fail to obtain approval of our drug candidates, the commercial prospects for our drug candidates may be harmed and our ability to earn revenue from arrangements with such third-party partners 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, our potential third-party partners 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. Our potential third-party partners 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 potential third-party partners' ability to obtain approval elsewhere. Our potential third-party partners 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 by our potential third-party partners internationally could harm our business.

If our drug candidates are marketed internationally by our potential third-party partners, if approved, our potential third-party partners would be subject to additional risks related to operating in foreign countries, 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 our drug candidates to foreign countries; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with international operations may compromise our ability to earn revenue from arrangements with potential third-party partners for our drug candidates.

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

Any drug candidate for which our potential third-party partners 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 by our potential third-party partners.

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 our potential third-party partners do not market our drugs for their approved indications, they 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;
- 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. These and other risks associated with the failure by our potential third-party partners to comply with regulatory requirements may compromise our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Our potential third-party partners' 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, and any failure to comply with such laws and regulations could have a material adverse effect on our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

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 drug candidates for which marketing approval is obtained. Our potential third-party partners' arrangements with third-party payors, health care professionals and customers may expose them 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 they sell, market and distribute any drug candidates for which marketing approval is obtained. In addition, we and our potential third-party partners 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 or they conduct business. The applicable federal, state and foreign health care laws and regulations that may affect our or our potential third-party partners' 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;
- federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which imposes criminal and civil liability for, among other things, executing a scheme to defraud any 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 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 or our potential third-party partners' 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 or our potential third-party partners' business practices, including relationships with physicians and other health care providers, some of whom may recommend, purchase and/or prescribe our drug candidates,

if approved, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other 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 or our potential third-party partners' operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us or them, we or our potential third-party partners may be subject to 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 requirements and oversight if we or they 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 or their operations, which could have a material adverse effect on our ability to earn revenue from arrangements with such third-party partners for our drug candidates. If any physician or other health care provider or entity with whom we or our potential third-party partners expect to do business is found not to be in compliance with applicable laws, it may be subject to significant criminal, civil or administrative sanctions, including exclusions from participation in government health care programs, which could also materially affect our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

Recently enacted and future legislation may increase the difficulty and cost for our potential third-party partners to obtain marketing approval of our drug candidates and commercialize our drug candidates, if approved, and affect the prices our potential third-party partners 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 potential third-party partners' ability to profitably sell any of our drug candidates for which our potential third-party partners obtain marketing approval, and consequently affect our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

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 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 commercial products 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.

There remain judicial and Congressional challenges to, as well as 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, or the 2017 Tax Act, 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, the 2020 federal spending package permanently eliminates, effective January 1, 2020, the Affordable Care Act-mandated "Cadillac" tax on high-cost employer-sponsored health coverage and medical device tax and, effective January 1, 2021, also eliminates the health insurer tax. 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 December 2018, CMS published a new 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 2017 Tax Act. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the Affordable Care Act are invalid as well. It is unclear how this decision, future decisions, 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 2029 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 our ability to earn revenue from arrangements with our potential third-party partners for our drug candidates.

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 our potential third-party partners receive for any approved drug candidate. 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 our potential third-party partners from being able to generate revenue, attain profitability, or commercialize our drug candidates, if approved, which in turn may impact our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

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 proposals for fiscal year 2020 contains further drug price control measures that could be enacted during the 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. The Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and, has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS' policy change that was effective January 1, 2019. While some of these and other measures may require additional authorization 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 obtaining marketing approvals for 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 our potential third-party partners to more stringent drug labeling and post-marketing testing and other requirements. These risks may compromise our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

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

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, our potential third-party partners 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 drug candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our potential third-party partners may not able to generate revenue, which in turn may adversely affect our ability to earn revenue from arrangements with such third-party partners for our drug candidates.

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 manufacturing 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 in 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 potential third-party partners' ability to compete in international markets or subject us or our potential third-party partners to liability if we or they are not in compliance with applicable laws.

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

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

Furthermore, if we or our third-party partners export our 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 may be time-consuming and may result in the delay or loss of sales opportunities. Failure to comply with export control and sanctions regulations may expose us or our potential third-party partners 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 and our potential third-party partners are subject to anti-corruption and anti-money laundering laws with respect to our and their operations and non-compliance with such laws can subject us to criminal and/or civil liability and harm our business.

We and our potential third-party partners 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. We or our potential third-party partners may engage third-party intermediaries in connection with the development or commercialization of our drug candidates and to obtain necessary permits, licenses and other regulatory approvals. We, our potential third-party partners or the 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. 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, manufacturing and clinical 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 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 and partner drug candidates. 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 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.

Our employees, independent contractors, consultants, third-party partners, 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, third-party partners, 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 by our potential third-party partners 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.

Risks Related to Ownership of Our Common Stock

An active trading market for our common stock may not be sustained.

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 be sustained. If an active market for our common stock 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.

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 of any of our drug candidates to receive marketing approval;
- unanticipated serious safety concerns related to the use of any drug candidate or previously sold commercial product;
- 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 the past, stockholders have initiated class action lawsuits against pharmaceutical companies following periods of volatility in the market prices of these companies' stock. For example, two purported class action complaints were filed against us and certain of our executive officers alleging violations of certain federal securities laws and two stockholder derivative actions were filed against certain of our executive officers and directors alleging breaches of fiduciary duties. We and the other defendants dispute the plaintiffs' claims and intend to defend these matters vigorously. We have entered into indemnity agreements with our executive officers and directors which provide, among other things, that we will indemnify such officer or director, under the circumstances and to the extent provided for therein, for expenses, damages, judgments, fines and settlements he or she may be required to pay in actions or proceedings which he or she is or may be made a party by reason of his or her position as our director, officer or other agent, and otherwise to the fullest

extent permitted under Delaware law and our bylaws. These cases, and additional litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If we fail to maintain compliance with the listing requirements of The Nasdaq Global Market, we may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted.

Our common stock is currently listed on The Nasdaq Global Market. To maintain the listing of our common stock on The Nasdaq Global Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $5 million and stockholders' equity of at least $10 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors, affiliates and 10% or more stockholders) of at least $15 million and a total market value of listed securities of at least $50.0 million.

We may fail to satisfy one or more Nasdaq Global Market requirements for continued listing of our common stock in the future. There can be no assurance that we will be successful in maintaining the listing of our common stock on the Nasdaq Global Market, or, if transferred, on the Nasdaq Capital Market. This could impair the liquidity and market price of our common stock. In addition, the delisting of our common stock from a national exchange could have a material adverse effect on our access to capital markets, and any limitation on market liquidity or reduction in the price of our common stock as a result of that delisting could adversely affect our ability to raise capital on terms acceptable to us, or at all.

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

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

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 currently expect that we will remain an emerging growth company until December 31, 2020.

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.

Changes in tax laws or regulations that are applied adversely to us may have a material adverse effect on our business, cash flow, financial condition or results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, which could adversely affect our business operations and financial performance. Further, existing tax laws, statutes, rules, regulations or ordinances could be interpreted, changed, modified or applied adversely to us. For example, the 2017 Tax Act enacted many significant changes to the U.S. tax laws. Future guidance from the Internal Revenue Service and other tax authorities with respect to the 2017 Tax Act may affect us, and certain aspects of the 2017 Tax Act could be repealed or modified in future legislation. In addition, it is uncertain if and to what extent various states will conform to the 2017 Tax Act or any newly enacted federal tax legislation. Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses under the 2017 Tax Act or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one-time charges, and could increase our future U.S. tax expense.

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, 2019, we had federal and state net operating loss carryforwards, or NOLs, of $326.1 million and $338.8 million, respectively, which will begin to expire in 2032. Under federal income tax law, federal NOLs incurred in 2018 and later years may be carried forward indefinitely, but the deductibility of such federal NOLs is limited. It is

uncertain if and to what extent various states will conform to the federal tax law. As of December 31, 2019, we also had federal research and development tax credit carryforwards of $7.3 million which will begin to expire in 2032, and state research and development tax credit carryforwards of $0.1 million which will begin to expire in 2022. These net operating loss and tax credit carryforwards could expire unused or due to limitation on use 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 NOLs generated from July 13, 2012 through December 31, 2018. Although we have experienced Section 382 ownership changes since 2012, we have concluded that we should have sufficient ability to utilize NOLs accumulated during the periods tested. We have not yet determined if a Section 382 ownership change has occurred during the year ended December 31, 2019, 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 might harm our future operating results by effectively increasing our future tax obligations.

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. 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 incur significant costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur, and will continue to incur, particularly after we cease to be an "emerging growth company," significant legal, accounting and other costs. These 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 the following types of actions or proceedings under Delaware statutory or common law: (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. However, this exclusive forum provision would not apply to suits brought to enforce a duty or liability created by the Securities Act or the Exchange Act. 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, which has a term through October 2023, which we use for our therapeutics business. If for any reason the lease between Chesterbrook Partners, LP, the Landlord, and Auxilium Pharmaceuticals, LLC, the Sublandlord, is terminated or expires prior to October 2023, our sublease will automatically terminate. We also sublease 21,056 square feet of office and laboratory space in St. Louis, Missouri, which has an initial term through June 2029, which we use for our therapeutics and contract research businesses. We have the option to extend the initial term for two additional periods of five years each. We believe that our facilities are suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

Securities Class Action

On July 30, 2019, plaintiff Linda Rosi, or Rosi, filed a putative class action complaint captioned *Rosi v. Aclaris Therapeutics, Inc., et al.* in the U.S. District Court for the Southern District of New York against us and certain of our executive officers. The complaint alleges that the defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA and find that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired our securities between May 8, 2018 and June 20, 2019.

On September 5, 2019, an additional plaintiff, Robert Fulcher, or Fulcher, filed a substantially identical putative class action complaint captioned *Fulcher v. Aclaris Therapeutics, Inc., et al.* in the same court against the same defendants.

On November 6, 2019, the court consolidated the Rosi and Fulcher actions, or together, the Consolidated Securities Action, and appointed Fulcher “lead plaintiff” for the putative class.

On January 24, 2020, Fulcher filed a consolidated amended complaint in the Consolidated Securities Action, naming two additional executive officers as defendants, extending the putative class period to August 12, 2019, and adding allegations concerning, among other things, alleged statements and omissions throughout the putative class period concerning ESKATA’s risks, tolerability and effectiveness. The defendants’ deadline to answer, move against or otherwise respond to the consolidated amended complaint is March 27, 2020.

We and the other defendants dispute plaintiffs’ claims in the Consolidated Securities Action and intend to defend the matter vigorously.

Stockholder Derivative Action

On November 15, 2019, plaintiff Keith Allred, or Allred, filed a derivative stockholder complaint captioned *Allred v. Walker et al.* in the U.S. District Court for the Southern District of New York against certain of our directors and executive officers. The complaint alleges that the defendants, among other things, breached their fiduciary duties as directors and/or officers in connection with the claims alleged in the Consolidated Securities Action. The complaint seeks, among other things, unspecified compensatory damages on behalf of our company.

On November 25, 2019, an additional plaintiff, Bruce Brown, or Brown, filed a substantially identical complaint captioned *Brown v. Walker et al.* in the same court against the same defendants.

On December 12, 2019, the court consolidated the Allred and Brown actions under the caption *In re Aclaris Therapeutics, Inc. Derivative Litigation*, or the Consolidated Derivative Action, and directed that future derivative cases filed in or transferred to the court arising out of substantially the same transactions or events be similarly consolidated. Thereafter, on January 11, 2020, the court stayed – subject to certain conditions – all deadlines in the Consolidated Derivative Action pending resolution of the defendants' anticipated motion to dismiss the Consolidated Securities Action.

The defendants dispute plaintiffs' claims in the Consolidated Derivative Action and intend to defend the matter vigorously.

Patent Infringement

On October 8, 2019, we, together with Allergan, Inc., filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Taro Pharmaceuticals, Inc., or Taro, related to an ANDA that Taro filed with the FDA to market a generic version of RHOFADE. The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for RHOFADE. We received a Paragraph IV Notice Letter from Taro dated August 28, 2019, advising that Taro had submitted an ANDA to the FDA seeking approval from the FDA to manufacture and market a generic version of RHOFADE prior to the expiration of the Orange Book-listed patents. Under our agreement with EPI Health for the purchase of RHOFADE, EPI Health agreed to file a motion to be substituted for us as a plaintiff party and has agreed to reimburse us for our reasonable fees and expenses so long as we remained a plaintiff party. On December 3, 2019, EPI Health was substituted for us as a plaintiff party.

In addition, from time to time, we are subject to litigation and claims arising in the ordinary course of business but, except as stated above, we are not currently a party to any material legal proceedings and we are not aware of any pending or threatened legal proceeding against us that we believe could have a material adverse effect on our business, operating results, cash flows or financial condition.

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 February 24, 2020, we had 41,528,822 shares of common stock outstanding held by 60 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

None.

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 immuno-inflammatory diseases. We currently have a pipeline of drug candidates focused on immuno-inflammatory diseases, as well as one product approved by the U.S. Food and Drug Administration, or FDA, that we are not currently distributing, marketing or selling, and other investigational drug candidates. In September 2019, we announced the completion of a strategic review of our business, as a result of which we are refocusing our resources on our immuno-inflammatory development programs. We plan to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates and ESKATA (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, our non-marketed FDA-approved product.

Since our inception, we have incurred significant operating losses. Our net loss was $161.4 million for the year ended December 31, 2019 and $132.7 million for the year ended December 31, 2018. As of December 31, 2019, we had an accumulated deficit of $453.5 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our drug candidates from discovery through preclinical and clinical development. In addition, our drug candidates, even if they are approved by regulatory agencies for marketing, may not achieve commercial success. We may also not be successful in pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our drug candidates or ESKATA. 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.

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, and subsequent public offerings of, and a private placement of, our common stock. In the near term, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including potential partnerships 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 of one or more of our drug candidates.

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 Janus Kinase, or JAK, inhibitors, ATI-501 and ATI-502, or the Rigel License Agreement, which we amended in October 2019. Under this agreement, we may develop these JAK inhibitors for the treatment of alopecia areata, or AA, and other dermatological conditions. We paid Rigel an upfront nonrefundable payment of $8.0 million in 2015 and $4.0 million upon the achievement of a specified development milestone in 2019. In addition, we have agreed to make remaining aggregate payments of up to $76.0 million upon the achievement of specified development milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional $10.5 million to Rigel upon the achievement of a second set of development milestones. In addition, in connection with the amendment of the agreement in October 2019, we agreed to pay Rigel an amendment fee of $1.5 million in three installments of $0.5 million in January 2020, April 2020 and July 2020, which is included in accrued expenses on our consolidated balance sheet. 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 Pharmaceuticals, Inc., or 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. 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 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. With respect to any covered products that we commercialize under 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 remaining contingent consideration of up to $75.0 million, based upon the achievement of specified regulatory and commercial milestones set forth in the Confluence Agreement. In addition, we have agreed to pay the former Confluence equity holders 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 marketed under the brand name ESKATA in the United States, in Canada for the treatment of seborrheic keratosis, or the Cipher License Agreement. 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. In September 2019, we and Cipher mutually terminated the Cipher License Agreement.

Asset Purchase Agreement with Allergan

In November 2018, we acquired RHOFADE (oxymetazoline hydrochloride) cream, 1%, or RHOFADE, which included an exclusive license to certain intellectual property for RHOFADE, as well as additional intellectual property, from Allergan Sales, LLC, or Allergan, pursuant to an 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. In addition, we 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. In addition, we agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. We incurred an aggregate expense of approximately $0.7 million and $0.2 million related to royalty payments under these agreements during the years ended December 31, 2019 and 2018, respectively.

Asset Purchase Agreement with EPI Health

In October 2019, we entered into an asset purchase agreement with EPI Health, LLC, or EPI Health, pursuant to which we sold the worldwide rights to RHOFADE, which included the assignment of certain licenses for related intellectual property assets, or the Disposition.

Pursuant to the asset purchase agreement, EPI Health paid us an upfront payment of $35.0 million, $1.75 million of which was placed in escrow, and $0.2 million for inventory. In addition, EPI Health has agreed to pay us (i) potential sales milestone payments of up to $20.0 million in the aggregate upon the achievement of specified levels of net sales of products covered by the agreement, (ii) a specified high single-digit royalty calculated as a percentage of net sales, on a product-by-product and country-by-country basis, until the date that the patent rights related to a particular product, such as RHOFADE, have expired, provided, that with respect to sales of RHOFADE in any territory outside of the United

States, such royalty shall be paid on a country-by-country basis until the date that the RHOFADE patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADE in such country and (iii) 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the Disposition in any territory outside of the United States, subject to specified exceptions. In addition, EPI Health has agreed to assume our obligation to pay specified royalties and milestone payments under our existing agreements with Allergan, Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc.

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 and 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 and related products at a low single-digit percentage of net sales, as defined in the agreement.

In August 2019, we voluntarily discontinued the commercialization of ESKATA in the United States and withdrew the marketing authorizations we had previously received for the product in all countries outside of the United States.

Components of Our Results of Operations

Revenue

Product Sales, net

We sold RHOFADE in the United States during the years ended December 31, 2019 and 2018. We relied on Allergan to distribute RHOFADE on our behalf pursuant to the terms of a transition services agreement. We sold RHOFADE to wholesalers in the United States, which, in turn, distributed it to pharmacies that ultimately filled patient prescriptions. We also entered into, or were subject to, arrangements with third-party payors, including pharmacy benefit managers and government agencies, as well as group purchasing organizations, or GPOs, which provided for government mandated or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of RHOFADE. We never sold RHOFADE outside of the United States. We sold the worldwide rights to RHOFADE to EPI Health in October 2019.

During the years ended December 31, 2019 and 2018, we sold ESKATA to one wholesaler, McKesson Specialty Care Distribution, or McKesson, which in turn resold ESKATA to health care providers. We also entered into agreements with two GPOs that provided for administrative fees and discounted pricing in the form of volume-based rebates and chargebacks. We never sold ESKATA outside of the United States. We discontinued sales of ESKATA in the United States in August 2019.

Product sales, net has been reclassified to discontinued operations for all periods presented.

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, 2019, there were no remaining funds available to us under the grants.

Cost of Revenue

Cost of revenue consists of the costs incurred in connection with the provision of contract research services to our clients through Confluence. Cost of revenue primarily includes:

- 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 active pharmaceutical ingredients and preclinical and clinical trial materials;
- outsourced professional scientific development services;
- medical affairs expenses related to our drug candidates, including investigator-initiated studies;
- 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.

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 to continue to incur research and development expenses in the near term as we continue the clinical development of ATI-450 as a potential treatment for rheumatoid arthritis and other immuno-inflammatory diseases, continue the development of our preclinical compounds, and continue to identify, research and develop additional drug candidates. 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 subjects;
- the number of subjects 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 preparation of regulatory filings for our drug candidates, and the expense of filing, prosecuting, defending and enforcing any patent claims or other intellectual property rights. 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 primarily consist of market research activities related to A-101 45% Topical Solution and our JAK inhibitors.

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, as well as payments made under a terminated related party sublease agreement and milestone payments under our finder's services agreement. We anticipate that we will incur increased director and officer insurance premiums and legal expenses associated with defending the current lawsuits described in this report.

Other Income (Expense), net

Other income (expense), 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 judgments 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. We only recognize revenue when collection of the consideration we are entitled to under a contract with a customer is probable.

Product Sales, net

We recognized revenue from product sales at the point the customer obtained control, which generally occurred upon delivery. We also included estimates of variable consideration in the same period revenue was recognized. Components of variable consideration included 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 was 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 considered all relevant information when estimating variable consideration such as contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of net revenue that can be recognized is constrained by estimates of variable consideration which are included in the transaction price. Payment terms with customers did not exceed one year and, therefore, we did not account for a financing component in our arrangements. We expensed incremental costs of obtaining a contract with a customer, including sales commissions, when incurred as the period of benefit was less than one year.

Trade Discounts and Allowances - We provided customers with trade discounts, rebates, allowances and/or other incentives. We recorded estimates for these items as a reduction of revenue in the same period the revenue was recognized.

Government and Payor Rebates – We contracted with, or were subject to arrangements with, certain third-party payors, including pharmacy benefit managers and government agencies, for the payment of rebates with respect to utilization of our commercial products. We also entered into agreements with GPOs that provided for administrative fees and discounted pricing in the form of volume-based rebates. We were also subject to discount and rebate obligations under state Medicaid programs and Medicare. We recorded estimates for these discounts and rebates as a reduction of revenue in the same period the revenue was recognized.

Other Incentives – We maintained a co-pay assistance program which was intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by third-party payors. We estimated and recorded accruals for these incentives as a reduction of revenue in the period the revenue was recognized. Our estimated amounts for co-pay assistance were based upon the number of claims and the cost per claim that we expected to receive associated with product that had been sold to customers but remained in the distribution channel at the end of each reporting period.

Product Returns - Consistent with industry practice, we have a product returns policy for RHOFADE 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 product to a patient. We recorded an estimate for the amount of product which may be returned as a reduction of revenue in the period the related revenue was recognized. Our estimates for product returns were based upon available industry data and our own sales information, including visibility into the inventory remaining in the distribution channel. There is no return liability associated with sales of ESKATA as we had a no returns policy for ESKATA when we commercialized it.

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

Intangible Assets

Our intangible assets include both definite-lived and indefinite-lived assets. Definite-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 definite-lived intangible assets consist of a research technology platform acquired through the acquisition of Confluence. Prior to the disposition in 2019, definite-lived intangible assets also included the intellectual property rights related to RHOFADE. Our indefinite-lived intangible assets consist of an in-process research and development, or IPR&D, drug candidate acquired through the acquisition of Confluence. IPR&D assets are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. The cost of IPR&D assets is either amortized over their estimated useful life beginning when the underlying drug candidate is approved and launched commercially, or expensed immediately if development of the drug candidate is abandoned.

Definite-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.

During the year ended December 31, 2019, we performed an impairment analysis of the RHOFADE intangible asset due to our decision to discontinue commercial operations and actively seek a commercialization partner for RHOFADE. Our impairment analysis, which primarily utilized a third-party indication of fair value, resulted in a fair value for the RHOFADE intangible asset which was less than its carrying value. As a result, we recorded an impairment charge of $27.6 million to adjust the carrying value of the RHOFADE intangible asset to its net realizable value.

Goodwill

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which we perform either during the fourth quarter or when indicators of an impairment are present. We consider each of our operating segments, therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. We attributed the full amount of the goodwill in connection with the acquisition of Confluence, or $18.5 million, to our therapeutics segment. We perform an impairment test annually which is a qualitative assessment based upon current facts and circumstances related to operations of the 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.

During the year ended December 31, 2019, we performed an impairment analysis due to the decline in our stock price, which was considered a triggering event to evaluate goodwill for impairment. Our impairment analysis, which utilized a market approach, noted that our stock price, including a reasonable control premium, resulted in a fair value for the therapeutics reporting unit which was less than its carrying value. As a result, we recorded an impairment charge of $18.5 million, the full balance of goodwill.

Leases

Leases represent a company’s right to use an underlying asset and a corresponding obligation to make payments to a lessor for the right to use those assets. We evaluate leases at their inception to determine if they are an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows are substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease.

We recognize assets and liabilities for leases at their inception based upon the present value of all payments due under the lease. We use an implicit interest rate to determine the present value of finance leases, and our incremental borrowing rate to determine the present value of operating leases. We determine incremental borrowing rates by

referencing collateralized borrowing rates for debt instruments with terms similar to the respective lease. We recognize expense for operating and finance leases on a straight-line basis over the term of each lease, and interest expense related to finance leases is recognized over the lease term based on the effective interest method. We include estimates for any residual value guarantee obligations under our leases in lease liabilities recorded on our consolidated balance sheet.

Right-of-use assets are included in other assets and property and equipment, net on our consolidated balance sheet for operating and finance leases, respectively. Obligations for lease payments are included in current portion of lease liabilities and other liabilities on our consolidated balance sheet for both operating and finance leases.

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.

During the year ended December 31, 2019, we updated our assumptions for contingent consideration related to the acquisition of Confluence as a result of the filing of an IND for ATI-450, which resulted in a charge of $0.7 million.

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 subjects, 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, 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, 2019 and 2018

	Year Ended December 31,		
	2019	2018	Change
	(In thousands)		
Revenues:			
Product sales, net	$ —	$ —	$ —
Contract research	4,227	4,651	(424)
Other revenue	—	1,500	(1,500)
Total revenue, net	4,227	6,151	(1,924)
Costs and expenses:			
Cost of revenue	4,055	4,329	(274)
Research and development	64,899	60,841	4,058
Sales and marketing	671	170	501
General and administrative	27,156	25,591	1,565
Goodwill impairment	18,504	—	18,504
Amortization of definite-lived intangible	—	—	—
Total costs and expenses	115,285	90,931	24,354
Loss from operations	(111,058)	(84,780)	(26,278)
Other income (expense), net	(2,484)	2,676	(5,160)
Loss from continuing operations	(113,542)	(82,104)	(31,438)
Loss from discontinued operations	(47,812)	(50,634)	2,822
Net loss	$ (161,354)	$ (132,738)	$ (28,616)

Revenue

Contract research revenue was $4.2 million and $4.7 million for the years ended December 31, 2019 and 2018, respectively, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence. Other revenue for the year ended December 31, 2018 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. Revenue from sales of ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

Cost of Revenue

Cost of revenue was $4.1 million and $4.3 million for the years ended December 31, 2019 and 2018, respectively, and related to providing laboratory services to our clients through Confluence. Cost of revenue for sales of ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

Research and Development Expenses

The following table summarizes our research and development expenses:

	Year Ended December 31,		
	2019	2018	Change
	(In thousands)		
A-101 45% Topical Solution	$ 13,309	$ 10,114	$ 3,195
JAK inhibitors	15,243	22,457	(7,214)
ATI-450	8,197	4,068	4,129
ESKATA	24	406	(382)
Personnel expenses	9,230	8,332	898
Restructuring expenses	382	—	382
Milestones and licensing expenses	5,500	—	5,500
Change in contingent consideration	734	1,272	(538)
Other research expenses	7,189	7,712	(523)
Stock-based compensation	5,091	6,480	(1,389)
Total research and development expenses	$ 64,899	$ 60,841	$ 4,058

Expenses related to A-101 45% Topical Solution increased primarily due to our two pivotal Phase 3 clinical trials, which were initiated during the third quarter of 2018 and were completed in September 2019 and October 2019, respectively. Development expenses related to our JAK inhibitors decreased primarily as a result of several Phase 2 clinical trials of ATI-501 and ATI-502 which were completed during the year ended December 31, 2019. The increase in expenses for ATI-450 resulted primarily from preclinical development activities as well as a Phase 1 clinical trial, which was initiated and near completion during the year ended December 31, 2019. The increase in personnel expenses was primarily the result of increased headcount prior to our restructuring. The decrease in stock-based compensation expense was primarily the result of forfeitures by certain employees during 2019. Restructuring expenses primarily included the cost of termination benefits given to employees that were involuntarily terminated during the year ended December 31, 2019. Milestones and licensing expenses consisted of $4.0 million related to the achievement of a development milestone under the Rigel License Agreement, as well as $1.5 million we agreed to pay to Rigel in connection with the amendment of the agreement. The change in contingent consideration was the result of updates to our assumptions related to drug discovery research on our soft-JAK inhibitors, which progressed more quickly than we had originally planned. Other research expenses, which primarily included expenses for medical affairs activities and drug discovery, decreased primarily as a result of lower medical affairs activities during the year ended December 31, 2019. Expenses related to ESKATA primarily consisted of stability testing. Expenses related to ESKATA for post-NDA approval activities have been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Year Ended December 31,		
	2019	2018	Change
	(In thousands)		
Direct marketing and professional fees	$ 663	$ 122	$ 541
Personnel expenses	—	—	—
Other sales and marketing expenses	8	48	(40)
Stock-based compensation	—	—	—
Total sales and marketing expenses	$ 671	$ 170	$ 501

Sales and marketing expenses primarily consisted of market research activities related to A-101 45% Topical Solution and our JAK inhibitors. Direct marketing and professional fees, personnel expenses, other sales and marketing expenses and stock-based compensation related to ESKATA and RHOFADE have been reclassified to discontinued

operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Year Ended December 31,		
	2019	2018	Change
	(In thousands)		
Personnel expenses	$ 7,735	$ 7,006	$ 729
Restructuring expenses	607	—	607
Professional and legal fees	3,995	5,091	(1,096)
Facility and support services	2,574	2,349	225
Other general and administrative expenses	1,957	1,828	129
Stock-based compensation	10,288	9,317	971
Total general and administrative expenses	$ 27,156	$ 25,591	$ 1,565

Personnel and stock-based compensation expenses increased due to increased headcount prior to our restructuring. Restructuring expenses primarily include the costs of termination benefits given to employees that were involuntarily terminated during the year ended December 31, 2019. Professional and legal fees included accounting, legal, investor relations and corporate communication costs, as well as legal fees related to patents and business development. The decrease in professional and legal fees was primarily related to lower corporate communications costs as well as lower legal costs incurred related to patents. Facility and support services included general office expenses and information technology costs, which increased due to our new office and laboratory facility in St. Louis, which we moved into during 2019, as well as increased headcount prior to our restructuring. Other general and administrative expenses included insurance, travel costs, depreciation and other miscellaneous expenses.

Goodwill Impairment

During the year ended December 31, 2019, we performed an impairment analysis due to the decline in our stock price. Our impairment analysis noted that our stock price, including a reasonable control premium, resulted in a fair value for the therapeutics reporting unit which was less than its carrying value. As a result, we recorded an impairment charge of $18.5 million writing off the full balance of goodwill.

Amortization of Definite-Lived Intangible

Amortization expense related to the intangible asset for RHOFADE intellectual property has been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

Other Income (Expense), net

The $5.2 million decrease in other income (expense), net was primarily due to interest expense incurred on our debt with Oxford, which we borrowed in October 2018. We repaid the debt in full in October 2019.

Comparison of Years Ended December 31, 2018 and 2017

	Year Ended December 31, 2018	2017	Change
		(In thousands)	
Product sales, net	$ —	$ —	$ —
Contract research	4,651	1,683	2,968
Other revenue	1,500	—	1,500
Total revenue, net	6,151	1,683	4,468
Costs and expenses:			
Cost of revenue	4,329	1,207	3,122
Research and development	60,841	35,804	25,037
Sales and marketing	170	85	85
General and administrative	25,591	18,948	6,643
Total costs and expenses	90,931	56,044	34,887
Loss from operations	(84,780)	(54,361)	(30,419)
Other income, net	2,676	2,070	606
Loss from continuing operations	(82,104)	(52,291)	(29,813)
Loss from discontinued operations	(50,634)	(18,062)	(32,572)
Benefit from income taxes	—	(1,830)	1,830
Net loss	$ (132,738)	$ (68,523)	$ (64,215)

Revenue

Contract research revenue was $4.7 million and $1.7 million for the years ended December 31, 2018 and 2017, respectively, and was comprised primarily of fees earned from the provision of laboratory services to clients through Confluence, which we acquired in August 2017. Other revenue for the year ended December 31, 2018 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. Revenue from sales of ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

Cost of Revenue

Cost of revenue was $4.3 million and $1.2 million for the years ended December 31, 2019 and 2018, respectively, and related to providing laboratory services to our clients through Confluence. Cost of revenue for sales of ESKATA and RHOFADE has been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

Research and Development Expenses

The following table summarizes our research and development expenses:

	Year Ended December 31,		
	2018	2017	Change
	(In thousands)		
A-101 45% Topical Solution	$ 10,114	$ 4,681	$ 5,433
JAK inhibitors	22,457	11,789	10,668
ATI-450	4,068	354	3,714
ESKATA	406	2,045	(1,639)
Personnel expenses	8,332	6,131	2,201
Change in contingent consideration	1,272	—	1,272
Other research expenses	7,712	5,333	2,379
Stock-based compensation	6,480	5,471	1,009
Total research and development expenses	$ 60,841	$ 35,804	$ 25,037

Expenses related to A-101 45% Topical Solution increased primarily due to the initiation of 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 continued to conduct multiple Phase 2 clinical trials of ATI-501 and ATI-502. Development expenses for ATI-450 increased as we performed IND-enabling preclinical studies and manufacturing scale-up activities in preparation for the initiation of clinical trials. 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 expenses primarily included expenses for medical affairs activities, 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 expenses was also driven by expenses related to our ITK inhibitor. Expenses related to ESKATA primarily consisted of stability testing and regulatory costs. The decrease in expenses related to ESKATA primarily related to the regulatory costs associated with the filing of the NDA, which occurred during the year ended December 31, 2017. Expenses related to ESKATA for post-NDA approval activities have been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

Sales and Marketing Expenses

The following table summarizes our sales and marketing expenses:

	Year Ended December 31,		
	2018	2017	Change
	(In thousands)		
Direct marketing and professional fees	$ 122	$ 85	$ 37
Personnel expenses	—	—	—
Other sales and marketing expenses	48	—	48
Stock-based compensation	—	—	—
Total sales and marketing expenses	$ 170	$ 85	$ 85

Sales and marketing expenses primarily consisted of market research activities related to A-101 45% Topical Solution and our JAK inhibitors. Direct marketing and professional fees, personnel expenses, other sales and marketing expenses and stock-based compensation related to ESKATA and RHOFADE have been reclassified to discontinued operations for all periods presented (see Note 18 to the consolidated financial statements included in this report for more information).

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Year Ended December 31,		
	2018	2017	Change
	(In thousands)		
Personnel expenses	$ 7,006	$ 4,378	$ 2,628
Professional and legal fees	5,091	3,631	1,460
Facility and support services	2,349	1,941	408
Milestone payment	—	1,000	(1,000)
Other general and administrative expenses	1,828	1,101	727
Stock-based compensation	9,317	6,897	2,420
Total general and administrative expenses	$ 25,591	$ 18,948	$ 6,643

Personnel and stock-based compensation expenses 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 associated with business development activities. Facility and support services included general office expenses and information technology costs which were higher due to our increased headcount as well as the relocation of our headquarters during the year ended December 31, 2018. 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. 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.

Benefit from Income Taxes

Benefit from income taxes was $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 well as debt financing that has since been repaid in full. We may engage in additional debt and equity financing transactions in order to raise additional funds. In addition, to the extent we are able to consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates or ESKATA, we may receive upfront payments, milestone payments or royalties from such arrangements that would increase our liquidity.

As of December 31, 2019, we had cash, cash equivalents and marketable securities of $75.0 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 sublease obligations, capital lease obligations and contingent obligations under acquisition and intellectual property licensing agreements, which are summarized below under "Contractual Obligations and Commitments."

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 common stock at a weighted average price per share of $31.50, for aggregate gross proceeds of $19.3 million. We paid underwriting discounts and commissions of $0.6 million, and 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 Agreement, with Oxford Finance LLC, or Oxford. The Loan Agreement provided for up to $65.0 million in term loans. Of the $65.0 million, we borrowed $30.0 million in October 2018. The Loan Agreement provided 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. The Loan Agreement provided 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 preceded the month in which the interest was to accrue plus 6.25%. The Loan Agreement also provided for a final payment equal to 5.75% of the original principal amount of the term loans drawn.

We had 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. In October 2019, we repaid in full the $30.0 million that was outstanding under the Loan Agreement and paid a prepayment fee of $0.6 million and a final payment fee of $1.7 million.

Cash Flows

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

	Year Ended December 31,		
	2019	2018	2017
	(In thousands)		
Net cash used in operating activities	$ (96,445)	$ (100,811)	$ (54,663)
Net cash provided by (used in) investing activities	105,679	9,367	(55,692)
Net cash provided by (used in) financing activities	(30,316)	128,261	100,386
Net increase (decrease) in cash and cash equivalents	$ (21,082)	$ 36,817	$ (9,969)

Operating Activities

During the year ended December 31, 2019, operating activities used $96.4 million of cash primarily resulting from our net loss of $161.4 million, partially offset by non-cash adjustments of $67.6 million. Net cash used by changes in our operating assets and liabilities during the year ended December 31, 2019 consisted of a $5.1 million decrease in accounts payable and accrued expenses and a $0.8 million increase in accounts receivable, which were partially offset by a $3.7 million decrease in prepaid expenses and other assets. The decrease in accounts payable and accrued expenses was primarily driven by lower levels of expenses, including sales discounts and allowances, as the result of the disposition of RHOFADE, and lower research and development expenses as a result of the completion of our two pivotal Phase 3 clinical trials for A-101 45% Topical Solution, as well as the timing of vendor invoicing and payments. The decrease in prepaid expenses and other assets was due to research and development activities primarily related to preclinical development activities for ATI-450 and ATI-502, which concluded during the year ended December 31, 2019, and the elimination of sales and marketing activities as a result of the disposition of RHOFADE in October 2019. The increase in accounts receivable was primarily the result of the timing of cash receipts from our contract research customers. Non-cash expenses of $67.6 million were composed of an intangible asset impairment charge of $27.6 million, a goodwill impairment charge of $18.5 million, stock-based compensation expense of $16.2 million, a charge of $0.7 million related to the change in the fair value of contingent consideration and depreciation and amortization expense of $6.4 million, partially offset by a gain of $1.9 million recognized on the disposition of RHOFADE.

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

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

Investing Activities

During the year ended December 31, 2019, investing activities provided $105.7 million of cash, consisting of proceeds from sales and maturities of marketable securities of $210.5 million and $34.2 million from the disposition of RHOFADE, partially offset by purchases of marketable securities of $137.4 million and purchases of equipment of $1.6 million.

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 acquisition of RHOFADE, and purchases of equipment of $1.4 million.

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

Financing Activities

During the year ended December 31, 2019, financing activities used $30.3 million of cash consisting of $30.0 million for the repayment of our term loan with Oxford and $0.5 million related to finance lease payments, partially offset by $0.2 million of cash received from the exercise of employee stock options.

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 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 finance 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 finance lease payments for laboratory equipment.

Funding Requirements

We anticipate we will incur net losses in the near term as we continue the clinical development of ATI-450 as a potential treatment for rheumatoid arthritis and other immuno-inflammatory diseases, continue the development of our preclinical compounds, and continue to identify, research and develop additional drug candidates. We may not be able to generate revenue from these programs if, among other things, our clinical trials are not successful, the FDA does not approve our drug candidates currently in clinical trials when we expect, or at all, or we are not able to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates.

Our primary uses of capital are, and we expect will continue in the near term to be, compensation and related expenses, clinical costs, external research and development services, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support 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, in particular after we cease to be an “emerging growth company” under the Jumpstart Our Business Startups Act of 2012, or JOBS Act, which we expect to occur on December 31, 2020.

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. We expect that we will require additional capital to complete the clinical development of ATI-450, to develop our preclinical compounds, and to support our discovery efforts. 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 or generate revenue from transactions with third-party partners for the development and/or commercialization of our drug candidates, we may need to substantially curtail our planned operations.

We may raise additional capital through the sale of equity or 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 and development of pharmaceutical drugs, we are unable to estimate the exact amount of our working capital requirements. Our funding requirements in the near term will depend on many factors, including:

- the number and development requirements of the drug candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our drug candidates;
- the costs, timing and outcome of regulatory review of our drug candidates;
- the extent to which we in-license or acquire additional drug candidates and technologies;
- 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;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, and earn revenue from such arrangements; and
- the revenue earned from our commercial products as a result of licenses to, or partnerships with, third parties.

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

Contractual Obligations and Commitments

We occupy space for our headquarters in Wayne, Pennsylvania under a sublease agreement which has a term through October 2023. We occupy office and laboratory space in St. Louis, Missouri under a sublease agreement which has a term through June 2029.

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.

Under the assignment agreement with the Estate of Mickey Miller pursuant to which we acquired intellectual property, we have agreed to pay royalties on sales of ESKATA and 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 with KPT Consulting, LLC, we have 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 and related products at a low single-digit percentage of net sales, as defined in the agreement. In August 2019, we voluntarily discontinued the commercialization of ESKATA in the United States and withdrew the marketing authorizations we had previously received for the product in all countries outside of the United States.

Under the Rigel License Agreement, we have agreed to make remaining aggregate payments of up to $76.0 million upon the achievement of specified development milestones, such as clinical trials and regulatory approvals. Further, we have agreed to pay up to an additional $10.5 million to Rigel upon the achievement of a second set of development milestones. In addition, in connection with the amendment of the agreement in October 2019, we agreed to pay Rigel an amendment fee of $1.5 million in three installments of $500,000 in January 2020, April 2020 and July 2020. 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 covered products that 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, 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.

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 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. We adopted this standard as of January 1, 2020, the impact of which on our consolidated financial statements was not significant.

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. We adopted this standard as of January 1, 2020, the impact of which on our consolidated financial statements was not significant.

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. We adopted this standard as of January 1, 2020, the impact of which on our consolidated financial statements was not significant.

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. We adopted this standard as of January 1, 2019, the impact of which on our consolidated financial statements was not significant.

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 model that requires a lessee to record a right-of-use asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are 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. The amendments in ASU 2016-02 must be applied to all leases existing at the date a company initially applies the standard.

We adopted the new standard as of January 1, 2019, using the effective date as the date of initial application, and we used the modified retrospective approach. In addition, we elected the practical expedients permitted under the transition guidance within the new standard, which, among other things, allowed us to carry forward the historical lease identification and classification. We also elected the practical expedient to not separate lease and non-lease components, as well as the short-term lease exemption which allowed us to not capitalize leases with terms less than 12 months that do not contain a reasonably certain purchase option. Our consolidated financial statements have not been updated, and disclosures required by the new standard have not been provided, for periods before January 1, 2019.

The adoption of ASU 2016-02 resulted in us recording additional assets and liabilities of $2.1 million and $2.3 million, respectively, upon adoption on January 1, 2019. The adoption of ASU 2016-02 did not have a material impact on our consolidated statement of operations or cash flows.

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

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.

Item 8. Financial Statements and Supplementary Data

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

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, 2019 and 2018, 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, 2019, 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, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2019 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
February 25, 2020

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, 2019	December 31, 2018
Assets		
Current assets:		
Cash, cash equivalents and restricted cash	$ 35,937	$ 57,019
Marketable securities	39,078	110,953
Accounts receivable, net	704	563
Inventory	—	—
Prepaid expenses and other current assets	3,118	4,802
Discontinued operations - current assets	4,966	6,162
Total current assets	83,803	179,499
Property and equipment, net	2,470	2,287
Intangible assets	7,199	7,274
Goodwill	—	18,504
Other assets	4,825	332
Discontinued operations - non-current assets	—	67,670
Total assets	$ 98,297	$ 275,566
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,917	$ 11,675
Accrued expenses	7,721	8,088
Current portion of lease liabilities	637	142
Discontinued operations - current liabilities	4,157	7,437
Total current liabilities	22,432	27,342
Other liabilities	3,736	476
Long-term debt	—	29,914
Contingent consideration	1,668	934
Deferred tax liability	549	549
Discontinued operations - non-current liabilities	—	1,227
Total liabilities	28,385	60,442
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at December 31, 2019 and December 31, 2018	—	—
Common stock, $0.00001 par value; 100,000,000 shares authorized at December 31, 2019 and December 31, 2018; 41,485,638 and 41,210,725 shares issued and outstanding at December 31, 2019 and December 31, 2018, respectively	—	—
Additional paid-in capital	523,505	507,366
Accumulated other comprehensive loss	(66)	(69)
Accumulated deficit	(453,527)	(292,173)
Total stockholders' equity	69,912	215,124
Total liabilities and stockholders' equity	$ 98,297	$ 275,566

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,		
	2019	2018	2017
Revenues:			
Product sales, net	$ —	$ —	$ —
Contract research	4,227	4,651	1,683
Other revenue	—	1,500	—
Total revenue, net	4,227	6,151	1,683
Costs and expenses:			
Cost of revenue	4,055	4,329	1,207
Research and development	64,899	60,841	35,804
Sales and marketing	671	170	85
General and administrative	27,156	25,591	18,948
Goodwill impairment	18,504	—	—
Amortization of definite-lived intangible	—	—	—
Total costs and expenses	115,285	90,931	56,044
Loss from operations	(111,058)	(84,780)	(54,361)
Other income (expense), net	(2,484)	2,676	2,070
Loss from continuing operations	(113,542)	(82,104)	(52,291)
Loss from discontinued operations	(47,812)	(50,634)	(18,062)
Loss before income taxes	(161,354)	(132,738)	(70,353)
Income taxes	—	—	(1,830)
Net loss	$ (161,354)	$ (132,738)	$ (68,523)
Net loss per share, basic and diluted	$ (3.90)	$ (4.03)	$ (2.44)
Weighted average common shares outstanding, basic and diluted	41,323,921	32,909,762	28,102,386
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities, net of tax of $0	$ 28	$ 145	$ (121)
Foreign currency translation adjustments	(25)	32	144
Total other comprehensive income	3	177	23
Comprehensive loss	$ (161,351)	$ (132,561)	$ (68,500)

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 Paid-in Capital	Accumulated Other Comprehensive Gain (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2016	26,059,181	—	260,671	(269)	(90,912)	169,490
Issuance of common stock under the at-the-market sales agreement, net of offering costs of $691	635,000	—	19,311	—	—	19,311
Issuance of common stock in connection with public offering, net of offering costs of $5,352	3,747,602	—	80,918	—	—	80,918
Issuance of common stock in connection with the acquisition of Confluence	349,527		9,675	—	—	9,675
Exercise of stock options and vesting of RSUs	65,195	—	(62)	—	—	(62)
Unrealized loss on marketable securities	—	—	—	(121)	—	(121)
Foreign currency translation adjustment	—	—	—	144	—	144
Stock-based compensation expense	—	—	14,430	—	—	14,430
Net loss	—	—	—	—	(68,523)	(68,523)
Balance at December 31, 2017	30,856,505	—	384,943	(246)	(159,435)	225,262
Issuance of common stock in connection with public offering, net of offering costs of $6,669	9,941,750	—	100,205	—	—	100,205
Issuance of common stock in connection with the Confluence development milestone	253,181	—	2,215	—	—	2,215
Exercise of stock options and vesting of RSUs	159,289	—	(52)	—	—	(52)
Unrealized gain on marketable securities	—	—	—	145	—	145
Foreign currency translation adjustment	—	—	—	32	—	32
Stock-based compensation expense	—	—	20,055	—	—	20,055
Net loss	—	—	—	—	(132,738)	(132,738)
Balance at December 31, 2018	41,210,725	$ —	$ 507,366	$ (69)	$ (292,173)	$ 215,124
Exercise of stock options and vesting of RSUs	274,913	—	(38)	—	—	(38)
Unrealized gain on marketable securities	—	—	—	28	—	28
Foreign currency translation adjustment	—	—	—	(25)	—	(25)
Stock-based compensation expense	—	—	16,177	—	—	16,177
Net loss	—	—	—	—	(161,354)	(161,354)
Balance at December 31, 2019	41,485,638	$ —	$ 523,505	$ (66)	$ (453,527)	$ 69,912

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,		
	2019	2018	2017
Cash flows from operating activities:			
Net loss	$ (161,354)	$ (132,738)	$ (68,523)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	6,409	1,879	402
Stock-based compensation expense	16,177	20,055	14,430
Change in fair value of contingent consideration	734	1,272	—
Goodwill impairment charge	18,504	—	—
Intangible asset impairment charge	27,638	—	—
Payment of Confluence development milestone	—	(717)	—
Gain on sale of RHOFADE	(1,850)	—	—
Deferred taxes	—	—	(1,837)
Changes in operating assets and liabilities:			
Accounts receivable	(809)	(4,380)	—
Inventory	605	102	—
Prepaid expenses and other assets	2,628	(40)	(4,306)
Accounts payable	(3,160)	6,964	4,564
Accrued expenses	(1,967)	6,792	607
Net cash used in operating activities	(96,445)	(100,811)	(54,663)
Cash flows from investing activities:			
Purchases of property and equipment	(1,613)	(1,356)	(1,235)
Acquisition of RHOFADE	—	(67,122)	—
Disposition of RHOFADE	34,186	—	—
Acquisition of Confluence, net of cash acquired	—	—	(9,647)
Purchases of marketable securities	(137,385)	(161,598)	(197,337)
Proceeds from sales and maturities of marketable securities	210,491	239,443	152,527
Net cash provided by (used in) investing activities	105,679	9,367	(55,692)
Cash flows from financing activities:			
Proceeds from issuance of common stock in connection with public offering, net of issuance costs	—	100,205	80,918
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	—	19,311
Proceeds from debt financing, net of issuance costs	—	29,910	—
Repayment of debt	(30,000)	—	—
Payment of Confluence development milestone	—	(1,783)	—
Finance lease payments	(523)	(648)	(78)
Proceeds from the exercise of employee stock options	207	577	235
Net cash (used in) provided by financing activities	(30,316)	128,261	100,386
Net increase (decrease) in cash and cash equivalents	(21,082)	36,817	(9,969)
Cash, cash equivalents and restricted cash at beginning of period	57,019	20,202	30,171
Cash, cash equivalents and restricted cash at end of period	$ 35,937	$ 57,019	$ 20,202
Supplemental disclosure of non-cash investing and financing activities:			
Additions to property and equipment included in accounts payable	$ 124	$ 161	$ 274
Operating lease asset recorded as a result of new accounting standard	$ 2,132	$ —	$ —
Fair value of stock issued in connection with Confluence development milestone	$ —	$ 2,215	$ —
Property and equipment obtained pursuant to finance lease financing arrangements	$ —	$ 2,131	$ —
Fair value of stock issued in connection with Confluence acquisition	$ —	$ —	$ 9,675
Offering costs included in accounts payable	$ —	$ 210	$ 20

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. Aclaris Therapeutics, Inc., ATIL, Vixen and Confluence are referred to collectively as the "Company". The Company is a physician-led biopharmaceutical company focused on immuno-inflammatory diseases. The Company currently has a pipeline of drug candidates focused on immuno-inflammatory diseases, as well as one product approved by the U.S. Food and Drug Administration ("FDA") that it is not currently distributing, marketing or selling, and other investigational drug candidates. In September 2019, the Company announced the completion of a strategic review of its business, as a result of which it is refocusing its resources on its immuno-inflammatory development programs. The Company plans to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize its drug candidates and ESKATA (hydrogen peroxide) topical solution, 40% (w/w) ("ESKATA"), the Company's non-marketed FDA-approved product.

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, 2019, the Company had cash, cash equivalents and marketable securities of $75,015 and an accumulated deficit of $453,527. 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 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, including clinical and preclinical testing of the Company's drug candidates, will require significant additional financing. The future viability of the Company is dependent on its ability to successfully develop its drug candidates and to generate revenue from identifying and consummating transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize its development assets or to raise additional capital to finance its operations. The Company expects that it will require additional capital to complete the clinical development of ATI-450, to develop its preclinical compounds, and to support its discovery efforts. 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 the Company to continue to implement its long-term business strategy. If the Company is unable to raise sufficient additional capital or generate revenue from transactions with third-party partners for the development and/or commercialization of its drug candidates, it may need to substantially curtail planned 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.

In accordance with Accounting Standards Update ("ASU") 2014-15, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern (Subtopic 205-40), the Company has evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern within one year after the date that its consolidated financial statements are issued. As of the report date, the Company believes the actions described below are probable of being implemented effectively and of alleviating the conditions or events that exist which raise substantial doubt about its ability to continue as a going concern within one year after the date of the issuance of these consolidated financial statements. The Company believes its existing cash, cash equivalents and marketable securities are sufficient to fund its operating and capital expenditure requirements for a period greater than 12 months from the date of issuance of these consolidated financial statements.

The Company has taken a number of actions to support its operations and meet its liquidity needs. In September 2019, the Company announced the completion of a strategic review and its decision to refocus its resources on its immuno-inflammatory development programs and to pursue strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize its drug candidates and ESKATA. As a result of this decision, the Company restructured its operations and terminated employees, some of which are occurring through termination dates into 2020, which will result in lower operating costs in the future. In October 2019, the Company sold the worldwide rights to RHOFADE to further its focus on its development programs and improve cash flow.

The Company's plans to further alleviate the substantial doubt about its going concern, which are probable of effectively being implemented and mitigating these conditions, primarily include its ability to control the timing and spending on its research and development programs. The Company may also consider other plans to fund its operations including: (1) raising additional capital through debt or equity financings; (2) identification of third-party partners to further develop, obtain marketing approval for and/or commercialize its drug candidates and ESKATA, which may generate revenue and/or milestone payments; (3) reducing spending on one or more research and development programs by delaying or discontinuing development; and/or (4) further restructuring its operations to change its overhead structure. Finally, 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 the Company to continue to implement its long-term business strategy.

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. Based upon the revenue from contract research services, the Company believes that gross profit does not provide a meaningful measure of profitability and, therefore, has not included a line item for gross profit on the consolidated statement of operations.

Discontinued Operations

In September 2019, the Company announced the completion of a strategic review and its decision to refocus its resources on its immuno-inflammatory development programs and to actively seek partners for its commercial products. The Company also announced a plan to terminate 86 employees (see Note 17).

The accompanying consolidated financial statements have been recast for all periods presented to reflect the assets, liabilities, revenue and expenses related to the Company's commercial products as discontinued operations (see Note 18). The accompanying consolidated financial statements are generally presented in conformity with the Company's historical format, even in certain situations where reclassifications to discontinued operations have resulted in $0 values being presented. The Company believes this format provides comparability with its previously filed financial statements.

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.

Product Sales, net

The Company sold RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE") and ESKATA (hydrogen peroxide) Topical Solution, 40% (w/w) ("ESKATA") during the years ended December 31, 2019 and 2018 to a limited number of wholesalers in the United States (collectively, its "Customers"). These Customers subsequently resold the Company's products to pharmacies and health care providers. In addition to distribution agreements with Customers, the Company entered into, or was subject to, arrangements with third-party payors, including pharmacy benefit managers and government agencies, as well as group purchasing organizations ("GPOs"), which provided for government mandated or privately negotiated rebates, chargebacks, and discounts with respect to the purchase of the Company's commercial products. The Company discontinued selling ESKATA in August 2019. The Company sold the worldwide rights to RHOFADE in October 2019 (see Note 3). Product sales, net has been reclassified to discontinued operations for all periods presented.

The Company recognized revenue from product sales at the point the Customer obtained control of the product, which generally occurred upon delivery. The Company also included estimates of variable consideration in the same period revenue was 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 was 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 considered all relevant information when estimating variable consideration such as contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. The amount of net revenue that can be recognized is constrained by estimates of variable consideration which are included in the transaction price. Payment terms with Customers did not exceed one year and, therefore, the Company did not account for a financing component in its arrangements. The Company expensed incremental costs of obtaining a contract with a Customer, including sales commissions, when incurred as the period of benefit was less than one year.

Trade Discounts and Allowances - The Company provided Customers with trade discounts, rebates, allowances and/or other incentives. The Company recorded estimates for these items as a reduction of revenue in the same period the revenue was recognized.

Government and Payor Rebates - The Company contracted with, or was subject to arrangements with, certain third-party payors, including pharmacy benefit managers and government agencies, for the payment of rebates with respect to utilization of its commercial products. The Company also entered into agreements with GPOs that provided for administrative fees and discounted pricing in the form of volume-based rebates. The Company was also subject to discount and rebate obligations under state Medicaid programs and Medicare. The Company recorded estimates for these discounts and rebates as a reduction of revenue in the same period the revenue was recognized.

Other Incentives - The Company maintained a co-pay assistance program which was intended to provide financial assistance to qualified commercially-insured patients with prescription drug co-payments required by third-party payors. The Company estimated and recorded accruals for these incentives as a reduction of revenue in the period the revenue was recognized. The Company estimated amounts for co-pay assistance based upon the number of claims and the cost per claim that the Company expected to receive associated with product that had been sold to Customers but remained in the distribution channel at the end of each reporting period.

Product Returns - Consistent with industry practice, the Company has a product returns policy for RHOFADE 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 product to a patient. The Company recorded an estimate for the amount of its products which may be returned as a reduction of revenue in the period the related revenue was recognized. The Company's estimate for product returns was based upon available industry data and its own sales information, including its visibility into the inventory remaining in the distribution channel. There is no return liability associated with sales of ESKATA as the Company had a no returns policy for ESKATA when it was commercialized.

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, 2019, 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, Cash Equivalents and Restricted Cash

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. Restricted cash as of December 31, 2019 included $1,750 placed in escrow pursuant to the asset purchase agreement with EPI Health, LLC ("EPI Health") (see Note 3).

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.

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 $0 and $791 of inventory as of December 31, 2019 and 2018, respectively, which was comprised primarily of finished goods and has been reclassified to discontinued operations for all periods presented.

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.

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 definite-lived and indefinite-lived assets. Definite-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. Definite-lived intangible assets consist of a research technology platform the Company acquired through the acquisition of Confluence. Prior to the disposition in 2019, definite-lived intangible assets also included the intellectual property rights related to RHOFADE. Indefinite-lived intangible assets consist of an in-process research and development ("IPR&D") drug candidate acquired through the acquisition of Confluence. IPR&D assets are considered indefinite-lived until the completion or abandonment of the associated research and development efforts. The cost of IPR&D is either amortized over its 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.

Definite-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 intangible asset is less than its carrying value.

During the year ended December 31, 2019, the Company performed an impairment analysis of the RHOFADE intangible asset due to its decision to discontinue commercial operations and actively seek a commercialization partner for RHOFADE. The Company's impairment analysis, which primarily utilized a market-participant's indication of fair value, resulted in a fair value for the RHOFADE intangible asset which was less than its carrying value. As a result, the Company recorded an impairment charge of $27,638, which is included in discontinued operations on the consolidated statement of operations, to adjust the carrying value of the RHOFADE intangible asset to its net realizable value (see Note 3).

Goodwill

Goodwill is not amortized, but rather is subject to testing for impairment at least annually, which the Company performs either during the fourth quarter or when indicators of an impairment are present. The Company considers each of its operating segments, therapeutics and contract research, to be a reporting unit since this is the lowest level for which discrete financial information is available. The Company attributed the full amount of the goodwill acquired with Confluence, or $18,504, to the 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 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.

During the year ended December 31, 2019, the Company performed an impairment analysis due to the decline in its stock price, which was considered a triggering event to evaluate goodwill for impairment. The Company's impairment analysis, using a market approach, noted that its stock price, including a reasonable control premium, resulted in a fair value for the therapeutics reporting unit which was less than its carrying value. As a result, the Company recorded an impairment charge of $18,504, the full balance of goodwill.

Leases

Leases represent a company's right to use an underlying asset and a corresponding obligation to make payments to a lessor for the right to use those assets. The Company evaluates leases at their inception to determine if they are an operating lease or a finance lease. A lease is accounted for as a finance lease if it meets one of the following five criteria: the lease has a purchase option that is reasonably certain of being exercised, the present value of the future cash flows are substantially all of the fair market value of the underlying asset, the lease term is for a significant portion of the remaining economic life of the underlying asset, the title to the underlying asset transfers at the end of the lease term, or if the underlying asset is of such a specialized nature that it is expected to have no alternative uses to the lessor at the end of the term. Leases that do not meet the finance lease criteria are accounted for as an operating lease.

The Company recognizes assets and liabilities for leases at their inception based upon the present value of all payments due under the lease. The Company uses an implicit interest rate to determine the present value of finance leases, and its incremental borrowing rate to determine the present value of operating leases. The Company determines incremental borrowing rates by referencing collateralized borrowing rates for debt instruments with terms similar to the respective lease. The Company recognizes expense for operating and finance leases on a straight-line basis over the term of each lease, and interest expense related to finance leases is recognized over the lease term based on the effective interest method. The Company includes estimates for any residual value guarantee obligations under its leases in lease liabilities recorded on its consolidated balance sheet.

Right-of-use assets are included in other assets and property and equipment, net on the Company's consolidated balance sheet for operating and finance leases, respectively. Obligations for lease payments are included in current portion of lease liabilities and other liabilities on the Company's consolidated balance sheet for both operating and finance leases.

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. 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 the Company's 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 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.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds all cash, cash equivalents and marketable securities balances at one accredited financial institution, in amounts that exceed federally insured limits. The Company does not believe that it is subject to unusual credit risk beyond the normal credit risk associated with commercial banking relationships.

The Company is dependent on third-party manufacturers to supply drug product, including all underlying components, for its 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 or 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 has two reportable segments, therapeutics and contract research, which are primarily based on its operating segments and operating results used to assess performance. The therapeutics segment is focused on 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 Accounting Pronouncements

In November 2018, the Financial Accounting Standards Board ("FASB") issued 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. The Company adopted this standard as of January 1, 2020, the impact of which on its consolidated financial statements was not significant.

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. The Company adopted this standard as of January 1, 2020, the impact of which on its consolidated financial statements was not significant.

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. The Company adopted this standard as of January 1, 2020, the impact of which on its consolidated financial statements was not significant.

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. The Company adopted the provisions of this standard as of January 1, 2019, the impact of which on its consolidated financial statements was not significant.

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 model that requires a lessee to record a right-of-use asset and a lease liability on the balance sheet for all leases with terms longer than 12 months. Leases are 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. The amendments in ASU 2016-02 must be applied to all leases existing at the date a company initially applies the standard.

The Company adopted the new standard as of January 1, 2019, using the effective date as the date of its initial application, and used the modified retrospective approach. In addition, the Company elected the practical expedients permitted under the transition guidance within the new standard which, among other things, allowed the Company to carry forward the historical lease identification and classification. The Company also elected the practical expedient to not separate lease and non-lease components, as well as the short-term lease practical expedient which allowed the Company

to not capitalize leases with terms less than 12 months that do not contain a reasonably certain purchase option. The Company's consolidated financial statements have not been restated, and disclosures required by the new standard have not been provided, for periods before January 1, 2019.

The adoption of ASU 2016-02 resulted in the Company recording additional assets and liabilities of $2,132 and $2,317, respectively, upon adoption on January 1, 2019. The adoption of ASU 2016-02 did not have a material impact on the Company's consolidated statement of operations or cash flows.

3. RHOFADE

Disposition - Asset Purchase Agreement with EPI Health, LLC

In October 2019, the Company entered into an asset purchase agreement with EPI Health pursuant to which the Company sold the worldwide rights to RHOFADE, which included the assignment of certain licenses for related intellectual property assets (the "Disposition").

Pursuant to the asset purchase agreement, EPI Health paid the Company an upfront payment of $35,000 ($1,750 of which was placed in escrow) and $200 for inventory. In addition, EPI Health has agreed to pay the Company (i) potential sales milestone payments of up to $20,000 in the aggregate upon the achievement of specified levels of net sales of products as defined in the asset purchase agreement, (ii) a specified high single-digit royalty calculated as a percentage of net sales, on a product-by-product and country-by-country basis, until the date that the patent rights related to a particular product, such as RHOFADE, have expired, provided, that with respect to sales of RHOFADE in any territory outside of the United States, such royalty shall be paid until the date that the RHOFADE patent rights in the particular country have expired or, if later, 10 years from the date of the first commercial sale of RHOFADE in such country and (iii) 25% of any upfront, license, milestone, maintenance or fixed payment received by EPI Health in connection with any license or sublicense of the assets transferred in the Disposition in any territory outside of the United States, subject to specified exceptions. Finally, EPI Health agreed to assume the Company's obligation to pay specified royalties and milestone payments under its existing agreements with Allergan Sales, LLC ("Allergan"), Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc.

Acquisition – Asset Purchase Agreement with Allergan Sales, LLC

In November 2018, the Company acquired the worldwide rights to RHOFADE, which included an exclusive license to certain intellectual property, from Allergan pursuant to an asset purchase agreement. The Company paid Allergan upfront cash consideration of $66,100. In addition, the Company 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. The Company also agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc.

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

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

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

The fair value of finished goods inventory acquired was estimated using net selling price less the costs of disposal and a reasonable profit for the disposal efforts. Raw material was valued at current replacement cost, which approximated the seller's carrying value. The intangible asset for the RHOFADE product rights was being amortized on a straight-line basis over a period of 10 years.

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, 2019			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 21,277	$ —	$ —	$ 21,277
Marketable securities	—	39,078	—	39,078
Total assets	$ 21,277	$ 39,078	$ —	$ 60,355
Liabilities:				
Acquisition-related contingent consideration	$ —	$ —	$ 1,668	$ 1,668
Total liabilities	$ —	$ —	$ 1,668	$ 1,668

	December 31, 2018			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 49,766	$ 4,992	$ —	$ 54,758
Marketable securities	—	110,953	—	110,953
Total assets	$ 49,766	$ 115,945	$ —	$ 165,711
Liabilities:				
Acquisition-related contingent consideration	$ —	$ —	$ 934	$ 934
Total liabilities	$ —	$ —	$ 934	$ 934

As of December 31, 2019 and 2018, 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. As of December 31, 2019 and 2018, the Company's marketable securities consisted of investments with maturities of more than three months and included commercial paper, corporate debt and government obligations, 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, 2019 and 2018, there were no transfers between Level 1, Level 2 and Level 3. The change in acquisition-related contingent consideration of $734 during the year ended December 31, 2019 was the result of updates to the Company's assumptions as a result of the filing of an Investigational New Drug Application ("IND") for ATI-450 during the year ended December 31, 2019.

As of December 31, 2019 and 2018, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

	December 31, 2019			
	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities	$ 7,815	$ 2	$ —	$ 7,817
Commercial paper	15,129	—	—	15,129
Asset-backed securities	8,004	4	—	8,008
U.S. government agency debt securities	8,126	1	(3)	8,124
Total marketable securities	$ 39,074	$ 7	$ (3)	$ 39,078

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

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

	December 31, 2019	December 31, 2018
Computer equipment	$ 1,315	$ 1,292
Finance lease right-of-use assets	435	—
Manufacturing equipment	—	604
Lab equipment	1,250	1,068
Furniture and fixtures	647	313
Leasehold improvements	889	332
Property and equipment, gross	4,536	3,609
Accumulated depreciation	(2,066)	(1,322)
Property and equipment, net	$ 2,470	$ 2,287

Depreciation expense was $1,511, $1,248 and $370 for the years ended December 31, 2019, 2018 and 2017, respectively.

6. Intangible Assets

Intangible assets consisted of the following:

	Remaining Life (years)	Gross Cost		Accumulated Amortization	
		December 31, 2019	December 31, 2018	December 31, 2019	December 31, 2018
Other intangible assets	7.6	751	751	181	106
Total definite-lived intangible assets		751	751	181	106
IPR&D	na	6,629	6,629	—	—
Total intangible assets		$ 7,380	$ 7,380	$ 181	$ 106

Amortization expense was $75, $75 and $31 for the years ended December 31, 2019, 2018 and 2017 respectively.

As of December 31, 2019, estimated future amortization expense is as follows:

Year Ending December 31,	
2020	$ 75
2021	75
2022	75
2023	75
2024	75
Thereafter	195
Total	$ 570

7. Accrued Expenses

Accrued expenses consisted of the following:

	December 31, 2019	December 31, 2018
Employee compensation expenses	$ 3,321	$ 4,948
Research and development expenses	2,857	1,437
Professional fees	168	1,123
Other	1,375	580
Total accrued expenses	$ 7,721	$ 8,088

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 provided for up to $65,000 in term loans (the "Term Loan Facility"). Of the $65,000, the Company borrowed $30,000 in October 2018. In October 2019, the Company repaid in full the $30,000 that was outstanding under the Loan Agreement, together with all accrued and unpaid interest and fees.

The Loan Agreement provided 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. The Loan Agreement provided 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 provided for a final payment fee equal to 5.75% of the original principal amount of the term loans drawn under the Term Loan Facility.

The carrying value of the Loan Agreement approximated fair value because the interest rate was a floating rate based on the 30-day U.S. LIBOR rate and was therefore reflective of market rates.

9. Stockholders' Equity

Preferred Stock

As of December 31, 2019 and 2018, 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, 2019 and 2018.

Common Stock

As of December 31, 2019 and 2018, 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, 2019.

At-The-Market Facility

In November 2016, the Company entered into a sales agreement with Cowen and Company, LLC ("Cowen"), pursuant to which Cowen acted as an agent in connection with sales of the Company's common stock from time to time under an "at-the-market" equity facility. In April 2017, the Company sold 635,000 shares of common stock 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. In October 2018, the Company 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, the Company entered into an underwriting agreement pursuant to which the Company issued and sold 3,747,602 shares of common stock under a 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 was permitted to 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, 2019, 817,586 shares remained available for grant under the 2015 Plan. As of January 1, 2020, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 1,451,997 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 745,735 and 984,761 were outstanding as of December 31, 2019 and 2018, 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, 2019, 2018 and 2017 were as follows:

	Year Ended December 31,		
	2019	2018	2017
Risk-free interest rate	2.27 %	2.66 %	1.93 %
Expected term (in years)	6.2	6.3	6.2
Expected volatility	99.36 %	96.78 %	94.19 %
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, 2019, 2018 and 2017:

	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
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
Granted	44,500	5.75		
Exercised	(142,779)	1.33		
Forfeited and cancelled	(1,081,581)	23.01		
Outstanding as of December 31, 2019	3,102,221	$ 20.33	6.55	$ 148
Options vested and expected to vest as of December 31, 2019	3,102,221	$ 20.33	6.55	$ 148
Options exercisable as of December 31, 2019	2,143,889 (1)	$ 19.48	5.93	$ 148

(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, 2019.

The weighted average grant date fair value of stock options granted during the years ended December 31, 2019, 2018 and 2017 was $4.63, $16.55 and $20.28 per share, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2019, 2018 and 2017.

	Number of Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding as of December 31, 2016	219,614	$ 27.43
Granted	117,883	26.27
Vested	(40,705)	26.89
Forfeited and cancelled	(13,239)	27.53
Outstanding as of December 31, 2017	283,553	$ 27.02
Granted	552,060	19.03
Vested	(140,497)	27.22
Forfeited and cancelled	(68,709)	23.65
Outstanding as of December 31, 2018	626,407	$ 20.30
Granted	3,650,942	3.56
Vested	(173,444)	21.31
Forfeited and cancelled	(510,990)	10.63
Outstanding as of December 31, 2019	3,592,915	$ 4.62

Stock-Based Compensation

Stock-based compensation expense included in total costs and expenses on the consolidated statement of operations included the following:

	Year Ended December 31,		
	2019	2018	2017
Cost of revenue	$ 703	$ 766	$ 211
Research and development	5,091	6,480	5,471
Sales and marketing	—	—	—
General and administrative	10,288	9,317	6,897
Total stock-based compensation expense	$ 16,082	$ 16,563	$ 12,579

As of December 31, 2019, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $13,150 and $12,195, respectively, which is expected to be recognized over weighted average periods of 1.81 years and 2.35 years, respectively.

11. Net Loss per Share

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

	Year Ended December 31,		
	2019	2018	2017
Numerator:			
Net loss	$ (161,354)	$ (132,738)	$ (68,523)
Denominator:			
Weighted average shares of common stock outstanding	41,323,921	32,909,762	28,102,386
Net loss per share, basic and diluted	$ (3.90)	$ (4.03)	$ (2.44)

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, 2019, 2018 and 2017. All share amounts presented in the table below represent the total number outstanding as of December 31 of each year.

	December 31,		
	2019	2018	2017
Options to purchase common stock	3,102,221	4,282,081	3,328,757
Restricted stock unit awards	3,592,915	626,407	283,553
Total potential shares of common stock	6,695,136	4,908,488	3,612,310

12. Leases

The Company has operating leases for office space and laboratory facilities, and finance leases for its laboratory equipment. As a result of the Company's decision to actively seek partners for its commercial products (see Note 3), the Company terminated the finance leases for its fleet vehicles and recognized a loss on lease termination of $248 during the year ended December 31, 2019. The components of lease expense were as follows:

	Year Ended December 31, 2019
Operating lease expense	$ 808
Finance Leases:	
Amortization of right-to-use assets	$ 443
Interest expense	87
Total finance lease expenses	$ 530

Rent expense was $987, $886 and $946 for the years ended December 31, 2019, 2018 and 2017, respectively, which was recognized on a straight-line basis over the term of the lease.

Operating Leases

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. The sublease has a term that runs through October 2023. If for any reason the lease between Chesterbrook

Partners, LP ("Landlord") and Sublandlord is terminated or expires prior to October 2023, the Company's sublease will automatically terminate.

In February 2019, the Company entered into a sublease agreement with a third party for 21,056 square feet of office and laboratory space in St. Louis, Missouri. The lease commenced in June 2019 and has a term that runs through June 2029.

Supplemental balance sheet information related to operating leases is as follows:

Operating Leases:	**December 31, 2019**
Gross cost	$ 5,213
Accumulated amortization	(480)
Operating lease right-of-use assets	$ 4,733
Other current liabilities	$ 526
Other liabilities	3,548
Total operating lease liabilities	$ 4,074

Finance Leases

Laboratory Equipment

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

Fleet Vehicles

The Company leased 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 began on the date the Company took delivery and continued for a period of four years. The Company returned all leased vehicles during the year ended December 31, 2019.

Supplemental balance sheet information related to finance leases is as follows:

Finance Leases:	**December 31, 2019**
Property and equipment, gross	$ 435
Accumulated depreciation	(322)
Property and equipment, net	$ 113
Other current liabilities	$ 111
Other liabilities	21
Total finance lease liabilities	$ 132

Supplemental information related to operating and finance leases is as follows:

	Year Ended December 31, 2019
Supplemental Cash Flow Lease Information:	
Operating cash flows from operating leases	$ 755
Operating cash flows from finance leases	87
Financing cash flows from finance leases	523
Leased assets obtained in exchange for new operating lease liabilities	$ 3,060
Weighted-Average Remaining Lease Term (in years):	
Operating leases	6.79
Finance leases	0.91
Weighted-Average Discount Rate:	
Operating leases	10.10 %
Finance leases	10.00 %

Future minimum lease payments under operating and finance lease agreements are as follows:

Year Ending December 31,	Operating Leases	Finance Leases
2020	$ 909	$ 116
2021	934	—
2022	959	—
2023	877	—
2024	354	—
Thereafter	1,670	—
Total undiscounted lease payments	5,703	116
Less: unrecognized interest	(1,629)	(5)
Total lease liability	$ 4,074	$ 111

The undiscounted lease payments presented in the table above are consistent with the future minimum lease payments disclosed in the Company's Annual Report on Form 10-K filed with the SEC on March 18, 2019 under the prior lease guidance, with the exception of the undiscounted lease payments related to leased vehicles, which were returned during the year ended December 31, 2019.

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, 2019, 2018 and 2017, the Company did not record an income tax benefit for net operating losses incurred in each year due to the uncertainty of realizing a benefit from those items.

Loss before income taxes is allocated as follows:

	Year Ended December 31,		
	2019	2018	2017
U.S. operations	$ (161,192)	$ (132,473)	$ (63,665)
Foreign operations	(162)	(265)	(6,688)
Loss before income taxes	$ (161,354)	$ (132,738)	$ (70,353)

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

	Year Ended December 31,		
	2019	2018	2017
Federal statutory income tax rate	(21.0)%	(21.0)%	(34.0)%
State taxes, net of federal benefit	(6.6)	(3.5)	(9.7)
Research and development tax credits	(1.5)	(2.1)	(1.1)
Permanent differences	3.0	0.8	0.4
Foreign rate differential	—	—	1.7
Change in deferred tax asset valuation allowance	26.2	25.7	17.4
Impact of U.S. tax reform	—	—	22.7
Effective income tax rate	0.1 %	(0.1)%	(2.6)%

Deferred tax liabilities, net consisted of the following:

	December 31,	
	2019	2018
Deferred tax assets:		
Net operating loss carryforwards	$ 90,298	$ 57,426
Capitalized start-up costs	6,904	6,954
Research and development tax credit carryforwards	7,417	5,038
Capitalized research and development expense	4,456	2,843
Stock-based compensation expense	12,973	9,037
Accrued compensation	588	923
Inventory	—	271
Other	618	683
Total deferred tax assets	123,254	83,175
Deferred tax liabilities:		
Property and equipment	(206)	(674)
Intangible asset	(1,741)	(1,735)
Section 481(a) adjustment	—	—
Other	(890)	(330)
Total deferred tax liabilities	(2,837)	(2,739)
Valuation allowance	(120,966)	(80,985)
Deferred tax liabilities, net	$ (549)	$ (549)

As of December 31, 2019, the Company had federal and state net operating loss ("NOL") carryforwards of $326,113 and $338,822, respectively, which will begin to expire in 2032. As of December 31, 2019, the Company also had federal research and development tax credit carryforwards of $7,323 which will begin to expire in 2032, and state research and development tax credit carryforwards of $118 which will begin to expire in 2022. The Company also has $1,675 of loss carryforwards in the United Kingdom which can be carried forward indefinitely. Utilization of the NOLs 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, 2018. 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 year ended December 31, 2019, 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, 2019 and 2018. 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, 2019, 2018 and 2017 related primarily to the increases in NOLs, capitalized start-up costs, and research and development tax credit carryforwards and were as follows:

	Year Ended December 31,		
	2019	2018	2017
Valuation allowance at beginning of year	$ (80,985)	$ (46,878)	$ (30,726)
Decreases recorded as benefit to income tax provision	—	—	—
Increases resulting from the acquisition of Confluence	—	—	(4,176)
Increases recorded to income tax provision	(39,981)	(34,107)	(11,976)
Valuation allowance as of end of year	$ (120,966)	$ (80,985)	$ (46,878)

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,		
	2019	2018	2017
Unrecognized tax benefits at beginning of year	$ —	$ 43	$ —
Increases related to prior year tax provisions	—		43
Decreases related to prior year tax provisions	—	(43)	—
Increases related to current year tax provisions	—	—	—
Unrecognized tax benefits as of end of year	$ —	$ —	$ 43

The total amount of unrecognized tax benefits that, if recognized, would impact the Company's effective tax rate were $0 as of December 31, 2019 and 2018. 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, 2019, 2018 and 2017, the Company recognized expense (benefit) of $0, $0 and $3, 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 NOLs 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

NeXeption, Inc.

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, 2019, 2018 and 2017, were $0, $570 and $318, 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. During the years ended December 31, 2019, 2018 and 2017, the Company incurred $0, $0 and $208 of net expenses for services provided by NST Consulting, LLC under the NST Services Agreement. The Company had no amounts payable to NST Consulting, LLC under the NST Services Agreement as of either December 31, 2019 or 2018.

Mr. Stephen Tullman, the former chairman of the Company's board of directors, is an executive officer of NeXeption and is also the manager of NST Consulting, LLC and NST, LLC, and certain of the Company's executive officers are and have been members of entities affiliated with NST, LLC.

Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc.

In November 2018, the Company acquired RHOFADE, including an exclusive license to certain intellectual property for RHOFADE as well as additional intellectual property, from Allergan pursuant to the terms of an asset purchase agreement.

Pursuant to the asset purchase agreement, the Company agreed to assume the obligation to pay specified royalties and milestone payments under agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. Certain current and former members of the Company's management team and board of directors are former holders of equity interests in Vicept Therapeutics, Inc. and Aspect Pharmaceuticals, LLC. In such capacities, these individuals may have been entitled to receive a portion of the potential future payments payable by the Company. In October 2019, the Company sold the worldwide rights to RHOFADE to EPI Health, who agreed to assume the Company's obligation to pay the royalties and milestone payments under its existing agreements with Aspect Pharmaceuticals, LLC and Vicept Therapeutics, Inc. The Company incurred an aggregate expense of $611, $51 and $0 related to royalty payments under these agreements during the years ended December 31, 2019, 2018 and 2017, respectively (see Note 3).

Mallinckrodt plc

In April 2018, Bryan Reasons was appointed to the Company's board of directors. Subsequently, in March 2019, Mr. Reasons became the Chief Financial Officer of Mallinckrodt plc. Prior to Mr. Reasons joining Mallinckrodt plc, the Company entered into a master services agreement with Mallinckrodt, LLC, a subsidiary of Mallinckrodt plc, in November 2018, pursuant to which Confluence provides laboratory services to Mallinckrodt in the ordinary course of business. Mr. Reasons was not involved in the negotiation or execution of the agreement, but may be deemed to have an interest in the ongoing transactions based on his employment as an executive officer of Mallinckrodt plc. During the years ended December 31, 2019 and 2018, the Company recorded revenue of $97 and $0, respectively, from Mallinckrodt under the master services agreement. Mr. Reasons had no financial interest in this transaction.

15. Agreements Related to Intellectual Property

Asset Purchase Agreement – Allergan Sales, LLC

In November 2018, the Company acquired RHOFADE from Allergan pursuant to an asset purchase agreement. The Company 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 to RHOFADE have expired or, if later, November 30, 2028. The Company incurred royalties earned by Allergan under the asset purchase agreement of $1,359, $114 and $0 during the years ended December 31, 2019, 2018 and 2017, respectively. The Company 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 October 2019, the Company sold the worldwide rights to RHOFADE to EPI Health, which agreed to assume the obligation to pay the royalties and milestone payments under the asset purchase agreement (see Note 3).

Agreement and Plan of Merger - Confluence

In August 2017, the Company entered into an Agreement and Plan of Merger, pursuant to which it acquired Confluence (the "Confluence Agreement"). In November 2018, the Company achieved a development milestone specified in the Confluence Agreement which was comprised of $2,500 in cash and 253,208 shares of its common stock with a fair value of $2,200. The Company also agreed to pay the former Confluence equity holders aggregate remaining contingent consideration of up to $75,000, based upon the achievement of specified regulatory and commercial milestones set forth in the Confluence Agreement. In addition, the Company agreed to pay the former Confluence equity holders 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 the Company sells, licenses or transfers any of the intellectual property acquired from Confluence pursuant to the Confluence Agreement to a third party, the Company 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) received from such sale, license or transfer in specified circumstances.

License and Collaboration Agreement – 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 two specified JAK inhibitors, which the Company refers to as ATI-501 and ATI-502. Under the agreement, the Company agreed to make aggregate payments of up to $80,000 upon the achievement of specified development milestones. During the year ended December 31, 2019, the Company made a milestone payment of $4,000 to Rigel upon the achievement of a specified development milestone which is included in research and development expenses on the Company's consolidated statement of operations. 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.

In connection with the amendment of the agreement in October 2019, the Company agreed to pay Rigel an amendment fee of $1,500 in three installments of $500 in January 2020, April 2020 and July 2020, which is included in accrued expenses on the Company's consolidated balance sheet as of December 31, 2019. In addition, the parties modified certain other development milestones, and the Company agreed to increase the potential payments payable upon the achievement of such milestones from $10,000 to $10,500 in the aggregate.

License, Development and Commercialization Agreement - 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 marketed under the brand name ESKATA in the United States, in Canada for the treatment of seborrheic keratosis. 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. In September 2019, the Company and Cipher mutually terminated the exclusive license agreement.

Assignment Agreement - Estate of Mickey Miller and Finder's Services Agreement - 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 A-101 45% Topical Solution and ESKATA. 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 a milestone payment of $1,000 upon the achievement of a specified regulatory milestone in April 2017, and a milestone payment of $1,500 upon the achievement of a specified commercial milestone in May 2018. 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 $14, $112 and $0 related to royalty payments under these agreements during the years ended December 31, 2019, 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.

Stock Purchase Agreement - Vixen Pharmaceuticals, Inc. and License Agreement - 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. 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 covered by the Vixen patent rights in the United States, the European Union and Japan, and aggregate payments of up to $22,500 upon the achievement of specified commercial milestones for products covered by the Vixen patent rights. With respect to any covered products that the Company commercializes under 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.

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 $740, $662, and $270 for the years ended December 31, 2019, 2018 and 2017, respectively.

17. Restructuring Charges

In September 2019, the Company announced the completion of a strategic review and its decision to refocus on its immuno-inflammatory development programs and to actively seek partners for its commercial products. As a result, the Company terminated 63 employees ("terminated employees") and gave notice to an additional 23 employees ("noticed employees") who were asked to provide transition services through termination dates ranging between 4 to 10 months from the date notice was given. The terminated employees were entitled to receive cash severance payments as well as cash payments in lieu of sixty days' notice required by the Worker Adjustment and Retraining Notification Act (the "WARN Act"). The noticed employees are entitled to receive one-time cash severance payments which are not contingent upon providing additional services to the Company. In addition, certain noticed employees can earn retention bonuses if they continue to be employed by the Company through certain termination dates. The Company recorded a restructuring charge for the one-time severance and WARN Act payments, which was triggered immediately upon either terminating or giving notice to the impacted employees. The Company is expensing the cost of retention bonuses for noticed employees over their respective service terms. During the year ended December 31, 2019, the Company recognized aggregate expenses of $2,748 and made payments of $2,316 related to termination benefits for employees explained above. The Company committed to paying up to $339 for contingent retention bonuses, of which $208 was accrued, as of December 31, 2019.

18. Discontinued Operations

The components of loss from discontinued operations as reported in the Company's consolidated statement of operations were as follows:

	Year Ended December 31,		
	2019	2018	2017
Revenues:			
Product sales, net	$ 13,896	$ 3,940	$ —
Total revenue, net	13,896	3,940	—
Costs and expenses:			
Cost of revenue (excludes amortization)	4,522	1,969	—
Research and development	503	2,168	3,986
Sales and marketing	23,112	47,827	13,684
General and administrative	2,929	2,058	392
Intangible asset impairment	27,638	—	—
Amortization of definite-lived intangible	4,426	552	—
Total costs and expenses	63,130	54,574	18,062
Loss from discontinued operations	(49,234)	(50,634)	(18,062)
Other income, net	1,422	—	—
Net loss from discontinued operations	$ (47,812)	$ (50,634)	$ (18,062)
Net loss from discontinued operations per share, basic and diluted	$ (1.16)	$ (1.54)	$ (0.64)
Weighted average common shares outstanding, basic and diluted	41,323,921	32,909,762	28,102,386

The following table presents the details of product sales, net included in discontinued operations:

	Year Ended December 31,		
	2019	2018	2017
ESKATA	$ 312	$ 2,804	$ —
RHOFADE	13,584	1,136	—
Total product sales, net	$ 13,896	$ 3,940	$ —

The following table presents information related to assets and liabilities reported as discontinued operations in the Company's consolidated balance sheet:

	December 31,	
	2019	2018
Accounts receivable, net	$ 4,966	$ 4,298
Inventory	—	791
Prepaid expenses and other current assets	—	1,073
Intangible asset held for sale	—	—
Discontinued operations - current assets	$ 4,966	$ 6,162
Property and equipment, net	$ —	$ 1,993
Intangible assets, net of accumulated amortization	—	65,677
Discontinued operations - non-current assets	$ —	$ 67,670
Accounts payable	$ 1,705	$ 3,080
Accrued expenses	2,452	3,898
Current portion of lease liabilities	—	459
Discontinued operations - current liabilities	$ 4,157	$ 7,437
Other liabilities	$ —	$ 1,227
Discontinued operations - non- current liabilities	$ —	$ 1,227

The following table presents certain non-cash items related to discontinued operations, which are included in the Company's consolidated statement of cash flows:

	Year Ended December 31,	
	2019	2018
Depreciation and amortization	$ 313	$ 269
Stock-based compensation expense	95	3,490
Intangible asset impairment charge	27,638	—
Loss on disposal of property and equipment	248	—
	28,294	3,759
Gain on sale of RHOFADE	1,670	—
Non-cash items, net	$ 26,624	$ 3,759

The Company relied on Allergan to distribute RHOFADE on its behalf pursuant to the terms of a transition services agreement. Accounts receivable, net as of December 31, 2019 and 2018 included $4,966 and $3,838, respectively, related to amounts invoiced by Allergan for sales of RHOFADE.

As a result of the Company's decision to actively seek partners for its commercial products, the Company terminated the finance leases for its fleet vehicles and recognized a loss on lease termination of $248 in the year ended December 31, 2019, which is included in other income, net in the Company's consolidated statement of operations.

During the year ended December 31, 2019, the Company performed an impairment analysis of the RHOFADE intangible asset due to its decision to discontinue commercial operations and actively seek a commercialization partner for RHOFADE. The Company's impairment analysis, which primarily utilized a third-party indication of fair value, resulted in a fair value for the RHOFADE intangible asset which was less than its carrying value. As a result, the Company recorded an impairment charge of $27,638 to adjust the carrying value of the RHOFADE intangible asset to its net realizable value.

19. Segment Information

The Company has two reportable segments, therapeutics and contract research. The therapeutics segment is focused on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases. 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, 2019, 2018 and 2017 are summarized in the tables below:

Year Ended December 31, 2019	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ 16,824	$ (12,597)	$ 4,227
Cost of revenue (excludes amortization)	—	16,253	(12,198)	4,055
Research and development	65,298	—	(399)	64,899
Sales and marketing	620	51	—	671
General and administrative	—	2,687	24,469	27,156
Goodwill impairment	18,504	—	—	18,504
Loss from operations	$ (84,422)	$ (2,167)	$ (24,469)	$ (111,058)
Loss from discontinued operations	$ (46,305)	$ —	$ (2,929)	$ (49,234)

Year Ended December 31, 2018	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ 1,500	$ 13,135	$ (8,484)	$ 6,151
Cost of revenue	—	11,399	(7,070)	4,329
Research and development	62,255	—	(1,414)	60,841
Sales and marketing	130	40	—	170
General and administrative	30	2,141	23,420	25,591
Loss from operations	$ (60,915)	$ (445)	$ (23,420)	$ (84,780)
Loss from discontinued operations	$ (48,576)	$ —	$ (2,058)	$ (50,634)

Year Ended December 31, 2017	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ 3,202	$ (1,519)	$ 1,683
Cost of revenue	—	2,726	(1,519)	1,207
Research and development	35,804	—	—	35,804
Sales and marketing	85	—	—	85
General and administrative	222	673	18,053	18,948
Loss from operations	$ (36,111)	$ (197)	$ (18,053)	$ (54,361)
Loss from discontinued operations	$ (17,670)	$ —	$ (392)	$ (18,062)

Intersegment Revenue

Revenue for the contract research segment included $12,597, $8,484 and $1,519 for services performed on behalf of the therapeutics segment for the years ended December 31, 2019, 2018 and 2017, respectively. All intersegment revenue has been eliminated in the Company's consolidated statement of operations.

20. Legal Proceedings

Securities Class Action

On July 30, 2019, plaintiff Linda Rosi ("Rosi") filed a putative class action complaint captioned *Rosi v. Aclaris Therapeutics, Inc., et al.* in the U.S. District Court for the Southern District of New York against the Company and certain of its executive officers. The complaint alleges that the defendants violated federal securities laws by, among other things, failing to disclose an alleged likelihood that regulators would scrutinize advertising materials related to ESKATA and find that the materials minimized the risks or overstated the efficacy of the product. The complaint seeks unspecified compensatory damages on behalf of Rosi and all other persons and entities that purchased or otherwise acquired the Company's securities between May 8, 2018 and June 20, 2019.

On September 5, 2019, an additional plaintiff, Robert Fulcher ("Fulcher"), filed a substantially identical putative class action complaint captioned *Fulcher v. Aclaris Therapeutics, Inc., et al.* in the same court against the same defendants.

On November 6, 2019, the court consolidated the Rosi and Fulcher actions (together, the "Consolidated Securities Action") and appointed Fulcher "lead plaintiff" for the putative class.

On January 24, 2020, Fulcher filed a consolidated amended complaint in the Consolidated Securities Action, naming two additional executive officers as defendants, extending the putative class period to August 12, 2019, and adding allegations concerning, among other things, alleged statements and omissions throughout the putative class period concerning ESKATA's risks, tolerability and effectiveness. The defendants' deadline to answer, move against or otherwise respond to the consolidated amended complaint is March 27, 2020.

The Company and the other defendants dispute plaintiffs' claims in the Consolidated Securities Action and intend to defend the matter vigorously.

Stockholder Derivative Action

On November 15, 2019, plaintiff Keith Allred ("Allred") filed a derivative stockholder complaint captioned *Allred v. Walker et al.* in the U.S. District Court for the Southern District of New York against certain of the Company's directors and executive officers. The complaint alleges that the defendants, among other things, breached their fiduciary duties as directors and/or officers in connection with the claims alleged in the Consolidated Securities Action. The complaint seeks, among other things, unspecified compensatory damages on behalf of the Company.

On November 25, 2019, an additional plaintiff, Bruce Brown ("Brown"), filed a substantially identical complaint captioned *Brown v. Walker et al.* in the same court against the same defendants.

On December 12, 2019, the court consolidated the Allred and Brown actions under the caption *In re Aclaris Therapeutics, Inc. Derivative Litigation* (the "Consolidated Derivative Action") and directed that future derivative cases filed in or transferred to the court arising out of substantially the same transactions or events be similarly consolidated. Thereafter, on January 11, 2020, the court stayed – subject to certain conditions – all deadlines in the Consolidated Derivative Action pending resolution of the defendants' anticipated motion to dismiss the Consolidated Securities Action.

The defendants dispute plaintiffs' claims in the Consolidated Derivative Action and intend to defend the matter vigorously.

Patent Infringement

On October 8, 2019, the Company, together with Allergan, Inc., filed a patent infringement lawsuit in the U.S. District Court for the District of Delaware against Taro Pharmaceuticals, Inc. ("Taro"), related to an Abbreviated New Drug Application ("ANDA") that Taro filed with the FDA to market a generic version of RHOFADE. The lawsuit claims infringement of U.S. Patent Nos. 7,812,049, 8,420,688, 8,815,929, 9,974,773 and 10,335,391, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book, for RHOFADE. The Company received a Paragraph IV Notice Letter from Taro dated August 28, 2019, advising that Taro had submitted an ANDA to the FDA seeking approval from the FDA to manufacture and market a generic version of RHOFADE prior to the expiration of the Orange Book-listed patents. Under the agreement with EPI Health for the purchase of RHOFADE, EPI Health agreed to file a motion to be substituted for the Company as a plaintiff party and has agreed to reimburse the Company for its reasonable fees and expenses so long as it remained a plaintiff party. On December 3, 2019, EPI Health was substituted for the Company as a plaintiff party.

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, 2019, 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, 2019, 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, 2019 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, 2019, 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 2020 Annual Meeting of Stockholders, or the 2020 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 2020 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 2020 Proxy Statement under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors" and "Information about our Executive Officers."

Item 11. Executive Compensation

The information required by Item 11 is hereby incorporated by reference to the sections of the 2020 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 2020 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 2020 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 2020 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm."

PART IV

Item 15. Exhibits, Financial Statement Schedules

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

(1) Financial Statements

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

(2) Financial Statement Schedules

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

(3) *Exhibits*

See exhibits listed under part (b) below.

(b) Exhibits

Exhibit Number	Description of Document
2.1#	Stock Purchase Agreement, by and among the Registrant, Vixen Pharmaceuticals, Inc., JAK1, LLC, JAK2, LLC, JAK3, LLC and Shareholder Representative Services LLC, dated as of March 24, 2016 (incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 11, 2016).
2.2#	Agreement and Plan of Merger, dated as of August 3, 2017, by and among the Registrant, Aclaris Life Sciences, Inc., Confluence Life Sciences, Inc. and Fortis Advisors LLC (incorporated by reference to Exhibit 2.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on November 7, 2017).
2.3^	Asset Purchase Agreement, by and between the Registrant and EPI Health, LLC, dated as of October 10, 2019 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 11, 2019).
3.1	Amended and Restated Certificate of Incorporation of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 13, 2015).
3.2	Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 13, 2015).
4.1	Specimen stock certificate evidencing shares of Common Stock (incorporated by reference to Exhibit 4.1 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
4.2*	Description of Securities.
10.1#	Clinical and Commercial Supply Agreement, by and between the Registrant and PeroxyChem LLC, dated as of August 6, 2014 (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015).
10.2#	Assignment Agreement, by and between the Registrant and Mickey J. Miller, II, as personal representative of the estate of Mickey J. Miller, dated as of August 20, 2012 (incorporated by reference to Exhibit 10.3 to Amendment No. 2 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on September 25, 2015).
10.3	Amendment to Assignment Agreement, by and between the Registrant and Mickey J. Miller, II, as personal representative of the estate of Mickey J. Miller, dated as of June 15, 2016 (incorporated herein by reference to Exhibit 10.25 to the Registrant's Registration Statement on Form S-1 (File No. 333-212095), filed with the SEC on June 2, 2016).

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 (incorporated by reference to Exhibit 10.11 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on March 18, 2019).
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 (incorporated by reference to Exhibit 10.12 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on March 18, 2019).
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+*	Second Amended and Restated Non-Employee Director Compensation Policy.
10.15+*	Third Amended and 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	First Amendment to License and Collaboration Agreement, by and between the Registrant and Rigel Pharmaceuticals, Inc. dated as of October 15, 2019 (incorporated by referenced to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on October 17, 2019).
10.18+	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).
10.19+	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).
10.20+*	Employment Agreement with Frank Ruffo, dated as of September 17, 2015.
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+	Form of Stock Option Grant Notice and Stock Option Agreement used in connection with the Aclaris Therapeutics, Inc. Inducement Plan (incorporated herein by reference to Exhibit 10.2 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on August 1, 2017).

10.25+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement used in connection with the Aclaris Therapeutics, Inc. Inducement Plan (incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on August 1, 2017).
10.26	Sublease, dated November 2, 2017, by and between the Registrant and Auxilium Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on November 2, 2017).
10.27	First Amendment to Sublease, dated as of December 13, 2017, by and between the Registrant and Auxilium Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on March 18, 2019).
10.28#	Commercial Supply Manufacturing Services Agreement, by and between the Registrant and James Alexander Corporation, dated as of January 24, 2018 (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 8, 2018).
21.1*	Subsidiaries of the Registrant.
23.1*	Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm.
24.1*	Power of Attorney (contained on signature page hereto).
31.1*	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as adopted pursuant to section 302 of the Sarbanes-Oxley Act of 2002.
32.1 *†	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Rules 13a-14(b) and 15d-14(b) promulgated under the Securities Exchange Act of 1934 and 18 U.S.C. Section 1350, as adopted pursuant to section 906 of The Sarbanes-Oxley Act of 2002.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

* Filed herewith.

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

\+ Indicates management contract or compensatory plan.

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

^ Pursuant to Item 601(a)(5) of Regulation S-K promulgated by the SEC, certain exhibits and schedules to this agreement have been omitted. The Company hereby agrees to furnish supplementally to the SEC, upon its request, any or all of such omitted exhibits or schedules. Pursuant to Item 601(b)(2)(ii) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted because such portions, indicated by asterisks, are both not material and would likely cause competitive harm to the Company if publicly disclosed. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of the exhibit.

 Pursuant to Item 601(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted because such portions, indicated by asterisks, are both not material and would likely cause competitive harm to the Company if publicly disclosed. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of this exhibit.

Item 16. Form 10-K Summary.

Not applicable.

SIGNATURES

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

ACLARIS THERAPEUTICS, INC.

By: /s/ Neal Walker
Neal Walker
President and Chief Executive Officer

Date: February 25, 2020

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

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

Signature	Title	Date
/s/ Neal Walker Neal Walker	President, Chief Executive Officer and Director *(Principal Executive Officer)*	February 25, 2020
/s/ Frank Ruffo Frank Ruffo	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 25, 2020
/s/ Christopher Molineaux Christopher Molineaux	Chairman of the Board of Directors	February 25, 2020
/s/ Anand Mehra, M.D. Anand Mehra, M.D.	Director	February 25, 2020
/s/ William Humphries William Humphries	Director	February 25, 2020
/s/ Andrew Powell Andrew Powell	Director	February 25, 2020
/s/ Andrew Schiff Andrew Schiff	Director	February 25, 2020
/s/ Bryan Reasons Bryan Reasons	Director	February 25, 2020
/s/ Maxine Gowen Maxine Gowen	Director	February 25, 2020

/s/ Vincent Milano Vincent Milano	Director	February 25, 2020

Exhibit 4.2

DESCRIPTION OF ACLARIS THERAPEUTICS, INC. CAPITAL STOCK

The following description of the common stock of Aclaris Therapeutics, Inc., or the Company, is a summary and does not purport to be complete. This summary is qualified in its entirety by reference to the provisions of the Delaware General Corporation Law, or the DGCL, and the complete text of the Company's amended and restated certificate of incorporation, or the certificate of incorporation, and amended and restated bylaws or the bylaws, which are incorporated by reference as Exhibits 3.1 and 3.2, respectively of the Company's Annual Report on Form 10-K to which this description is also an exhibit. The Company encourages you to read that law and those documents carefully.

Common Stock

Under the certificate of incorporation, the Company authorized to issue up to 100,000,000 shares of common stock, $0.00001 par value per share, and 10,000,000 shares of preferred stock, $0.00001 par value per share, all of which shares of preferred stock are undesignated. The Company's board of directors may establish the rights and preferences of the preferred stock from time to time.

Voting Rights

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

Dividends

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

Liquidation

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

Rights and Preferences

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

Anti-Takeover Provisions

Section 203 of the DGCL

The Company is subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding, but not the outstanding voting stock owned by the interested stockholder, those shares owned (i) by persons who are directors and also officers and (ii) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock that is not owned by the interested stockholder.

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

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition of 10% or more of the assets of the corporation involving the interested stockholder;
- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;
- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits by or through the corporation.

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

Certificate of Incorporation and Bylaws

The certificate of incorporation provides for the Company's board of directors to be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because the Company's stockholders do not have cumulative voting rights, stockholders holding a majority of the shares of common stock outstanding will be able to elect all of the Company's directors. The certificate of incorporation and bylaws also provide that directors may be removed by the stockholders only for cause upon the vote of 66 2/3% or more of outstanding common stock. Furthermore, the authorized number of directors may be changed only by resolution of the board of directors, and vacancies and newly created directorships on the board of directors may, except as otherwise required by law or determined by the board, only be filled by a majority vote of the directors then serving on the board, even though less than a quorum.

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

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

The certificate of incorporation and bylaws provide that the stockholders cannot amend many of the provisions described above except by a vote of 66 2/3% or more of outstanding common stock.

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

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

Transfer Agent and Registrar

The transfer agent and registrar for the Company's common stock is Broadridge Corporate Issuer Solutions, Inc. The transfer agent's address is 1717 Arch Street, Suite 1300, Philadelphia, Pennsylvania 19103.

Listing on the NASDAQ Global Select Market

The Company's common stock is listed on the Nasdaq Global Select Market under the symbol "ACRS."

ACLARIS THERAPEUTICS, INC.

SECOND 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 Second Amended & Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service effective as of October 30, 2019 (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

4. Annual Chairman of the Board Service Retainer (in addition to Board Service Retainer): $27,500

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 22,000 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

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].

ACLARIS THERAPEUTICS, INC.

THIRD 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 Third Amended & Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service effective as of the date of the Company's 2020 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

4. Annual Chairman of the Board Service Retainer (in addition to Board Service Retainer): $27,500

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 33,000 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 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 16,500 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].

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "Employment Agreement"), effective as of, and contingent upon, the effectiveness of the registration statement for Employer's initial public offering ("Agreement Effective Date"), is made by and between Aclaris Therapeutics, Inc., a corporation organized under the laws of the State of Delaware ("Employer") and Frank Ruffo ("Executive").

WHEREAS, Executive desires to continue to provide services to Employer and Employer desires to continue to retain the services of Executive;

WHEREAS, in consideration of Executive's employment by Employer for more than three (3) years prior to the Agreement Effective Date, Employer and Executive desire to enter this Employment Agreement and formalize the terms and conditions of Executive's employment with Employer; and

WHEREAS, this Agreement has been duly approved and its execution has been duly authorized by the Compensation Committee of Employer's Board of Directors.

NOW, THEREFORE, Employer and Executive hereby agree as follows:

1
EMPLOYMENT

1.1 General. Employer hereby agrees to continue to employ Executive in the capacity of Chief Financial Officer. Executive hereby accepts such continued employment upon the terms and subject to the conditions herein contained.

1.2 Authority and Duties. Executive shall have full responsibility as the Chief Financial Officer of Employer and all authority normally accorded to such position. Executive agrees to perform such duties and responsibilities commensurate with the position of Chief Financial Officer as may reasonably be determined by the Board of Directors of Employer (the "Board").

1.2.1 Reporting. During Executive's employment with Employer, Executive will report directly to, and take direction from, the Chief Executive Officer (the "CEO").

1.2.2 Time to Be Devoted to Employment. During Executive's Employment with Employer, Executive shall diligently devote his efforts, business time, attention and energies to the business of Employer will not, while employed by Employer, undertake or engage in any other employment, occupation or business enterprise that would interfere with Executive's responsibilities and the performance of Executive's duties hereunder except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Executive may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties; and (iii) such other activities as may be specifically approved by the Board. This restriction shall not, however, preclude Executive (x) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (y) from employment or service in

any capacity with Affiliates of Employer. As used in this Agreement, "Affiliates" means an entity under common management or control with Employer.

1.3 Other Responsibilities. Notwithstanding Section 1.2.2 above, the Board expressly grants Executive the right to (i) provide services as a member (or such other such role as he may later serve) of NeXeption, Inc. and its affiliated entities; (ii) provide services to Alexar Therapeutics, Inc.; and (iii) perform services, if necessary, for companies other than Employer, in connection with his ownership interests in such companies; provided that the provision of such services does not adversely affect his performance of services hereunder and does not otherwise result in a material breach hereunder.

1.4 Location of Employment. Executive's principal place of employment during his employment with Employer shall be in Malvern, Pennsylvania or such other location as Employer and Executive shall agree.

2
COMPENSATION AND BENEFITS

2.1 Salary. Employer will pay to Executive an annual base salary of two hundred forty thousand, four hundred fifty-three Dollars and fifty Cents ($240,453.50), payable subject to standard federal and state payroll withholding requirements in accordance with the regular payroll practices of Employer ("Base Salary"). The annual Base Salary may be increased (but not decreased) during the term of this Employment Agreement by the Board in its sole discretion.

2.2 Additional Compensation. In addition to the salary set forth in Section 2.1, Executive shall be entitled to receive a cash bonus in accordance with the terms of this Section 2.2. For each fiscal year of Employer, beginning January 1, during the Employment Term (as defined in Section 2.4 hereof), Executive shall be eligible to receive a cash bonus based on (i) the "Annual Bonus Expectancy Amount," which shall be an amount equal to thirty percent (30%) of Executive's Base Salary for the applicable fiscal year, and (ii) Executive's attainment of performance targets and other reasonable criteria established by the Board, to the extent possible, by the end of the first month of such fiscal year. Depending on the targets and criteria which are achieved or met, the amount of the cash bonus actually payable to Executive for each fiscal year will be an amount from zero to and including the Annual Bonus Expectancy Amount. Any cash bonus amount payable pursuant to this Section 2.2 shall be paid to Executive as soon as practicable, but in no event later than two and one-half (2 1/2) months, following the end of the fiscal year to which it relates. It is explicitly agreed and understood that cash bonuses under this Section 2.2 are to be payable only if, and to the extent, that the Board in its judgment determines Employer has adequate cash flow and is adequately capitalized to support such payment.

2.3 Executive Benefits. In addition to the salary and additional compensation set forth in Sections 2.1 and 2.2, Executive shall also be entitled to the following benefits during Executive's employment hereunder:

2.3.1 Expenses. Employer will promptly reimburse Executive for expenses he reasonably incurs in connection with the performance of his duties (including business travel and

entertainment expenses), in accordance with Employer's standard expense reimbursement policy, as the same may be modified by Employer from time to time; provided, however, that Executive has provided Employer with documentation of such expenses in accordance with the Employer's expense reimbursement policies and applicable tax requirements. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A of the Code: (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

2.3.2 Employer Plans. Executive will be eligible to participate on the same basis as similarly situated employees in Employer's employee benefit plans and programs, as they may be interpreted, adopted, revised or deleted from time to time in Employer's sole discretion, subject to and on a basis consistent with the terms, conditions and overall administration of such plans and programs. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of such plan. Employer retains the unilateral right to amend, modify or terminate any of its employee benefit plans and programs at any time.

2.3.3 Vacation. Executive shall be eligible for paid vacation leave (not including regular holidays) consistent with the needs of the business. Vacation must be scheduled at those times convenient to Employer's business as reasonably determined by the CEO.

2.3.4 Coverage. Nothing in this Employment Agreement shall prevent Executive from participating in any other compensation plan or benefit plan made available to him by Employer.

2.3.5 Withholding. All compensation shall be subject to withholding of taxes and deductions of other amounts as may be required by law.

2.4 Employment Term. Unless earlier terminated pursuant to Section 3.1, Executive's employment by Employer pursuant to this Employment Agreement shall continue until the second anniversary of the Agreement Effective Date (the "Initial Term"). Thereafter, this Employment Agreement shall be automatically renewed for successive one (1) year periods (the Initial Term, together with any subsequent employment period being referred to herein as the "Employment Term"); provided, however, that either party may elect to not renew this Employment Agreement by written notice to such effect delivered to the other party at least ninety (90) days prior to expiration of the Initial Term or the Employment Term.

3
TERMINATION OF EMPLOYMENT

3.1 Events of Termination. Executive's employment with Employer will terminate upon the occurrence of any one or more of the following events:

3.1.1 Death. In the event of Executive's death, Executive's employment will terminate on the date of death.

3.1.2 Disability. In the event of Executive's Disability (as hereinafter defined), Employer will have the option to terminate Executive's employment by giving a notice of termination to Executive. The notice of termination shall specify the date of termination, which date shall not be earlier than thirty (30) calendar days after the notice of termination is given. For purposes of this Employment Agreement, "Disability" means the failure or inability of Executive to substantially perform, with or without reasonable accommodation, his duties hereunder for an aggregate of ninety (90) calendar days during any consecutive three hundred sixty-five (365) day period as a result of a physical or mental illness or injury, as determined in good faith by the Board upon the advice of an independent physician experienced in treating the condition(s) allegedly giving rise to the disability. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law.

3.1.3 Termination by Employer for Cause. Employer may, at its option, terminate Executive's employment for Cause by unilateral action of the Board of Directors upon giving a notice of termination to Executive. "Cause" shall mean (i) Executive's conviction of, or guilty plea to, a crime of moral turpitude (whether or not a felony) or a felony (other than traffic violations); (ii) any act(s) or omission(s) by Executive which constitutes gross negligence or a material breach of Executive's duty of loyalty; (iii) any material breach by Executive of Employer's personnel policies, including those prohibiting acts of discrimination, harassment or retaliation; (iv) any act constituting dishonesty, fraud, immoral or disreputable conduct; (v) refusal to follow or implement a clear and reasonable directive of Employer; (vi) breach of fiduciary duty; or (vii) a material violation or breach by Executive of this Employment Agreement (other than an event described in the foregoing clauses (i) through (vi)) or any other agreement between the parties.

3.1.4 Without Cause By Employer. Employer may, at its option, terminate Executive's employment for any reason whatsoever (other than for the other reasons set forth above in this Section 3.1 that would constitute "Cause" to terminate) by giving a notice of termination to Executive, and Executive's employment shall terminate on the later of the date the notice of termination is given or the date set forth in such notice of termination.

3.1.5 By Executive. Executive may, at any time, terminate Executive's employment for any reason whatsoever by giving a notice of termination to Employer. Executive's employment shall terminate on the earlier of (i) the date, following the date of the notice of termination, upon which a suitable replacement for Executive is found by the Employer or upon which Employer makes a determination, in its sole discretion, that Executive's duties shall be undertaken by other employees of Employer, (ii) thirty (30) calendar days after the date of receipt by Employer of the notice of termination, or (iii) such earlier date as the Employer and Executive shall agree.

3.1.6 Termination Upon Non-Renewal. Either party may terminate this Employment Agreement and Executive's employment hereunder by providing the other party notice in accordance with Section 2.4 above, in which case this Employment Agreement and

Executive's employment hereunder shall terminate on the last date of the Initial Term or the Employment Term, as the case may be. For the avoidance of doubt, Executive shall continue to be employed by Employer, on the same terms and conditions as set forth in this Employment Agreement during the ninety (90)-day notice period provided by either party to the other party in accordance with Section 2.4 above, unless, Employer, in its sole discretion determines that it does not want Executive to continue to work for Employer, in any capacity, during such notice period. In such event, Employer shall pay Executive all compensation in accordance with Section 3.2.3.

3.1.7 For Good Reason by Executive. Executive may, at his option, terminate Executive's employment for "Good Reason" by giving a notice of termination to Employer in the event that, in the absence of events that would support a termination of Executive for Cause:

(i) there is a material failure of Employer (or successor employer) to pay Executive's salary or additional compensation or benefits hereunder in accordance with this Employment Agreement;

(ii) Executive's annual Base Salary is materially decreased without his prior written consent;

(iii) Executive is assigned duties substantially inconsistent with his title and the responsibilities set forth in Executive's job description, without Executive's prior written consent;

(iv) Executive's place of employment is changed to a location that is greater than fifty (50) miles from Executive's current place of employment which is contemplated to be 101 Lindenwood Drive, Suite 400, Malvern, Pennsylvania 19355; or

(v) any other material violation or breach by Employer of this Employment Agreement.

Notwithstanding the foregoing, none of the events described in clauses (i) through (v) above shall constitute Good Reason unless Executive shall have notified Employer in writing describing the event which constitute Good Reason within thirty (30) days after Executive first becomes aware of such event and then only if Employer and/or its subsidiaries shall have failed to reasonably cure such events, if curable, within thirty (30) days after Employer's receipt of such written notice and Executive elects to terminate his employment as a result within thirty (30) days following the end of such thirty (30) day period (assuming, for the avoidance of doubt, that Employer does not elect to cure).

3.2 Certain Obligations of Employer Following Termination of Executive's Employment. Following the termination of Executive's employment under the circumstances described below, Employer will pay to Executive, subject to standard federal and state payroll withholding requirements and in accordance with its regular payroll practices, the following compensation and provide the following benefits (provided that the continuing payments of Executive's then-current salary, as described below, shall occur no less frequently than monthly):

3.2.1 Death; Disability; Termination by Employer Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated by Employer pursuant to Section 3.1.1 ("Death"), Section 3.1.2 ("Disability"), Section 3.1.4 ("Without Cause by Employer") or by Executive pursuant to Section 3.1.7 ("Termination by Executive for Good Reason") hereof, and Executive, or his estate, as the case may be, executes and does not revoke a separation agreement containing a release upon such termination, in a form provided by the Employer, of any and all claims against Employer and all related parties with respect to all matters arising out of Executive's employment by Employer, or the termination thereof (the "Release") in accordance with Section 3.7, Executive, or his estate, as the case may be, shall be entitled to the following payments and benefits, which payments and benefits shall be paid in accordance with this Section 3.2.1 and Section 3.7:

(i) Continuing payments of Executive's then-current salary for the Severance Period, as defined in Section 3.5 herein, payable subject to standard federal and state payroll withholding requirements in accordance with Employer's regular payroll practices on Employer's normal payroll schedule over the Severance Period, subject to Section 3.7;

(ii) Employer shall pay to Executive a lump sum payment equal to the gross sum of any bonuses or portion thereof for any preceding year or for the year of termination which have been approved by Employer, but has not been received by Executive prior to the effective date of termination, less applicable deductions and withholdings paid in accordance with Section 2.2 but in no event later than two and one-half (2 1/2) months following the end of the fiscal year to which it relates. For the avoidance of doubt, (x) Executive does not have to be employed by Employer on the date such bonuses are approved by Employer to receive such bonuses; and (y) this provision shall not be construed as guaranteeing the payment of a bonus for such year(s);

(iii) So long as Executive is eligible, and so long as Executive remains eligible, for and upon his timely election of coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or, if applicable, state or local insurance laws ("COBRA"), Employer will continue to pay, directly to the healthcare provider when due, 100% of the medical, vision and dental coverage premiums (including employee contributions, if any) until the earlier of (i) the end of the Severance Period; or (ii) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment (the "COBRA Payment Period"); provided that Executive must immediately notify Employer in the event Executive becomes eligible for coverage under another employer's group health plan during the COBRA Payment Period; and provided further that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for the remainder of the COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA Payment Period; and

(iv) In the event such termination of employment occurs on or within three (3) months prior to or within twelve (12) months following the effective date of a Change of Control (as defined herein), Executive shall be entitled to the additional following payments and benefits:

(1) Continuing payments of Executive's then-current salary for an additional six (6) months following the end of the Severance Period, payable subject to standard federal and state payroll withholding requirements in accordance with Employer's regular payroll practices on Employer's normal payroll schedule over the six (6) month period immediately following the end of the Severance Period, subject to Section 3.7;

(2) Continued payment of Executive's COBRA premiums directly to the healthcare provider for an additional six (6) months following the end of the Severance Period, or if earlier, until the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment, subject to the terms, conditions and payment provisions set forth in Section 3.2.1(iii); and

(3) In the event such termination of employment occurs (A) on or within three (3) months prior to the effective date of a Change of Control (as defined herein), all unvested stock options and other equity awards held by Executive and outstanding on the effective date of termination shall become fully vested on the effective date of the Change of Control, or (B) within twelve (12) months following the effective date of a Change of Control, provided that any surviving corporation or acquiring corporation assumes Executive's stock options and/or other equity awards, as applicable, or substitutes similar stock options or equity awards for Executive's stock options and/or equity awards, as applicable, in accordance with the terms of Employer's applicable equity incentive plans, all such unvested stock options and other equity awards held by Executive and outstanding on the effective date of termination shall become fully vested on the date of such termination.

For purposes of this Agreement, "Change of Control" means, in each case as approved by the Board and the requisite stockholders of Employer, (i) any consolidation or merger of Employer with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of Employer immediately prior to such consolidation, merger or reorganization, own, in the aggregate, less than 50% of the surviving entity's voting power and/or outstanding capital stock immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions (including any transaction which results from an option agreement or binding letter of intent with a third party) to which Employer or any of its stockholders is a party in which in excess of 50% of Employer's voting power and/or outstanding capital stock is transferred, or pursuant to which any person or group of affiliated persons obtains in excess of 50% of Employer's voting power and/or outstanding capital stock, excluding any consolidation or merger effected exclusively to change the domicile of Employer; or (ii) any sale, lease or other disposition (including through a Board and stockholder approved division or spin-off transaction) of all or substantially all of the assets of Employer and/or any of its subsidiaries or any sale, lease, exclusive license (or substantially exclusive license or agreement) or other disposition of all or substantially all of Employer's intellectual property, as reasonably determined based upon the potential earning power of the assets or intellectual property; provided, however that none of the following shall

constitute a Change of Control: (A) transfers of capital stock by an existing stockholder as a result of death or otherwise for estate planning purposes or to such stockholder's affiliates or to any of Employer's other existing stockholders, and (B) issuances of equity securities of Employer in connection with financings for working capital and other general corporate purposes.

3.2.2 Termination by Executive Other than For Good Reason: Termination Upon Non-Renewal by Executive; Termination by Employer for Cause. In the event Executive's employment is terminated by Executive other than for Good Reason pursuant to Section 3.1.5 hereof ("By Executive") or by Executive pursuant to Section 3.1.6 hereof ("Termination Upon Non-Renewal") or by Employer pursuant to Section 3.1.3 hereof ("Termination by Employer for Cause"), Executive shall be entitled to no further compensation or other benefits under this Employment Agreement except as to that portion of any unpaid salary and other benefits accrued and earned by him hereunder up to and including the effective date of such termination and to offer COBRA coverage at Executive's cost pursuant to applicable law.

3.2.3 Termination Upon Non Renewal by Employer. In the event Executive's employment is terminated by Employer pursuant to Section 3.1.6 hereof, then during the ninety (90)-day notice period of Section 2.4, Employer shall continue to pay to Executive his then-current annual Base Salary and benefits subject to standard federal and state payroll withholding requirements and in accordance with Employer's regular payroll practices and no later than the effective date of termination of employment, Employer shall pay to Executive any unpaid salary accrued and earned by him up to and including the effective date of termination. In addition, in the event Executive's employment is terminated by Employer pursuant to Section 3.1.6 hereof, then provided Executive executes and does not revoke a Release in accordance with Section 3.7, Executive shall be entitled to the following, which payments and benefits shall be paid in accordance with this Section 3.2.3 and Section 3.7:

(i) continuing payments of Executive's then-current salary for the Severance Period payable subject to standard federal and state payroll withholding requirements in accordance with Employer's regular payroll practices on Employer's normal payroll schedule over the Severance Period, subject to Section 3.7;

(ii) Employer shall pay to Executive a lump sum payment equal to the gross sum of any bonuses or portion thereof for any preceding year or for the year of termination which bonus has been approved by Employer, but has not been received by Executive prior to the effective date of termination, less applicable deductions and withholdings paid in accordance with Section 2.2 but in no event later than two and one-half (2 1/2) months following the end of the fiscal year to which it relates. For the avoidance of doubt, (x) Executive does not have to be employed by Employer on the date such bonuses are approved by the Employer to receive such bonuses; and (y) this provision shall not be construed as guaranteeing the payment of a bonus for such year(s); and

(iii) So long as Executive is eligible, and so long as Executive remains eligible, for and upon his timely election of COBRA coverage, Employer will continue to pay, directly to the healthcare provider when due, 100% of the medical, vision and dental

coverage premiums (including employee contributions, if any) until the earlier of (i) the end of the five (5) month period following the effective date of termination; or (ii) the date when Executive becomes eligible for substantially equivalent health insurance coverage in connection with new employment (the "Nonrenewal COBRA Payment Period"); provided that Executive must immediately notify Employer in the event Executive becomes eligible for coverage under another employer's group health plan during the Nonrenewal COBRA Payment Period; and provided further that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for the remainder of the Nonrenewal COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the Nonrenewal COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the Nonrenewal COBRA Payment Period.

3.3 Nature of Payments. All amounts to be paid by Employer to Executive pursuant to Sections 3.2.1(i) – (iv) and 3.2.3(i) – (iii) are considered by the parties to be severance payments and are in lieu of, and not in addition to, any benefits to which Executive may otherwise be entitled under any Employer severance plan, policy or program.

3.4 Duties Upon Termination. During the Severance Period, if there is a Severance Period applicable to Executive's termination of employment from Employer, Executive shall fully cooperate with Employer in all matters relating to the winding up of Executive's pending work including, but not limited to, any litigation in which Employer is involved, and the orderly transfer of any such pending work to such other employees as may be designated by Employer. Notwithstanding the foregoing, such cooperation requirement shall not unreasonably interfere with his then current employment or business activities. With Employer's prior approval, Executive shall be reimbursed for all expenses reasonably incurred in connection with such cooperation. Following the end of the Severance Period, Executive will be released from any duties and obligations hereunder (except those duties and obligations set forth in Article 4 hereof). In the event of termination of Executive's employment pursuant to Sections 3.1.1 through 3.1.7 hereof, the obligations of Employer to Executive will be as set forth in Section 3.2 hereof.

3.5 Severance Period. "Severance Period" shall mean a period of nine (9) months beginning on and immediately following the effective date of Executive's termination of employment with Employer.

3.6 Release. Notwithstanding any provision of this Employment Agreement to the contrary, in no event shall the timing of Executive's execution of the Release, directly or indirectly, result in Executive designating the calendar year of payment, and if a payment that is subject to the requirements of Section 409A of the Code and is subject to execution of the Release could be made in more than one taxable year based on when the Release is executed or becomes effective, payment shall be made in the later year.

3.7 Commencement of Severance Payments. The severance payments and benefits set forth in Sections 3.2.1(i) – (iv) (Termination by Employer for Death, Disability, Without Cause, by Executive for Good Reason) and Sections 3.2.3(i) – (iii) (Termination Upon Non-Renewal by Employer) above will not be paid or provided unless Executive executes and does not revoke the Release and the Release is enforceable and effective as provided in the Release on or before the date that is the sixtieth (60^{th}) day following the effective date of termination (such 60^{th} day, the "Severance Pay Commencement Date"). No cash severance payments will be paid pursuant to Sections 3.2.1 or 3.2.3 prior to the Severance Pay Commencement Date. On the Severance Pay Commencement Date Employer will pay in a lump sum the aggregate amount of the cash severance payments that Employer would have paid Executive through such date had the payments commenced on the effective date of termination through the Severance Pay Commencement Date, with the balance paid thereafter on the applicable schedules described above. Notwithstanding any other provision of this Agreement to the contrary, it is intended that the payment of severance upon termination for Good Reason by Executive in accordance with Section 3.1.7 satisfy the safe harbor set forth in Treasury Regulation Section 1.409A-1(n)(2)(ii)), and any severance payment made pursuant to this Agreement shall satisfy the exemptions from the application of Section 409A of the Code provided under Treasury Regulation Sections 1.409A-1(b)(4), and 1.409A-1(b)(9).

4
CONFIDENTIALITY; NON-COMPETITION AND NON-SOLICITATION;

4.1 Confidentiality and Invention Rights. The parties hereto have entered into a Confidentiality and Invention Rights, Non-Competition and Non-Solicitation Agreement, which may be amended by the parties from time to time without regard to this Agreement. The Confidentiality and Invention Rights, Non-Competition and Non-Solicitation Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

4.2 Remedies. Executive acknowledges and agrees that (a) Employer will be irreparably injured in the event of a breach by Executive of any of his obligations under this Article 4; (b) monetary damages will not be an adequate remedy for any such breach; and (c) in the event of any such breach, the Employer will be entitled to injunctive relief, in addition to any other remedy which it may have, and Executive shall not oppose such injunctive relief based upon the extent of the harm or the adequacy of monetary damages.

5
MISCELLANEOUS PROVISIONS

5.1 Severability. If in any jurisdiction any term or provision hereof is determined to be invalid or unenforceable, (a) the remaining terms and provisions hereof shall be unimpaired, (b) any such invalidity or unenforceability in any jurisdiction shall not invalidate or render unenforceable such provision in any other jurisdiction, and (c) the invalid or unenforceable term or provision shall, for purposes of such jurisdiction, be deemed replaced by a term or provision that is valid and enforceable and that comes closest to expressing the intention of the invalid or unenforceable term or provision.

5.2 Execution in Counterparts. This Employment Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original but all of which taken together shall constitute one and the same agreement (and all signatures need not appear on any one counterpart), and this Employment Agreement shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto.

5.3 Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed duly given when delivered by hand, or when delivered if mailed by registered or certified mail, postage prepaid, return receipt requested, or private courier service or via facsimile (with written confirmation of receipt) or email (with written confirmation of receipt) as follows:

If to Employer, to:

Aclaris Therapeutics, Inc.
101 Lindenwood Drive, Suite 400
Malvern, Pennsylvania 19355
Attention: Kamil Ali-Jackson, Esq.
Email: kalijackson@aclaristx.com
Telephone: 484-324-7933

If to Executive, to:

Frank Ruffo
223 Prince William Way
Chalfont, Pennsylvania 18914
Email: fruffo@aclaristx.com

or to such other address(es) as a party hereto shall have designated by like notice to the other parties hereto.

5.4 Amendment. No provision of this Employment Agreement may be modified, amended, waived or discharged in any manner except by a written instrument executed by Employer and Executive.

5.5 Entire Agreement. This Employment Agreement constitutes the entire agreement of the parties hereto with respect to the subject matter hereof, and supersedes all prior agreements and understandings of the parties hereto, oral or written, with respect to the subject matter hereof, including but not limited any prior offer letter or written embodiment of the employment relationship between Executive and Employer and the letter from Employer to Executive entitled “Change of Control Bonus” dated August 30, 2012. No representation, promise or inducement has been made by either party that is not embodied in this Employment Agreement, and neither party shall be bound by or liable for any alleged representation, promise or inducement not so set forth.

5.6 Applicable Law. This Employment Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania applicable to

contracts made and to be wholly performed therein without regard to its conflicts or choice of law provisions.

5.7 Headings. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Employment Agreement.

5.8 Binding Effect; Successors and Assigns. Executive may not delegate his duties or assign his rights hereunder. This Employment Agreement will inure to the benefit of, and be binding upon, the parties hereto and their respective heirs, legal representatives, and successors. Employer may assign this Employment Agreement to any entity purchasing all or substantially all of the assets of Employer.

5.9 Waiver, etc. The failure of either of the parties hereto to at any time enforce any of the provisions of this Employment Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Employment Agreement or any provision hereof or the right of either of the parties hereto to thereafter enforce each and every provision of this Employment Agreement. No waiver of any breach of any of the provisions of this Employment Agreement shall be effective unless set forth in a written instrument executed by the party against whom or which enforcement of such waiver is sought, and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.

5.10 Continuing Effect. Provisions of this Agreement which by their terms must survive the termination of this Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the term, termination of Executive's employment, or otherwise, for such period as may be appropriate under the circumstances.

5.11 Representations and Warranties of Executive. Executive hereby represents and warrants to Employer that to the knowledge of Executive, Executive is not bound by any non-competition or other agreement which would prevent his performance hereunder.

5.12 Section 409A of the Code. This Employment Agreement is intended to comply with Section 409A of the Code and its corresponding regulations, or an exemption, and payments may only be made under this Employment Agreement upon an event and in a manner permitted by Section 409A of the Code, to the extent applicable. Payment under this Employment Agreement is intended to be exempt from Code Section 409A under the "short-teen deferral" exception set forth in Treasury Regulation Section 1.409A-1(b)(4), to the maximum extent applicable, and then under the "separation pay" exception set forth in Treasury Regulation Section 1.409A-1(b)(9), to the maximum extent applicable. All payments to be made upon a termination of employment under this Agreement may only be made upon a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h) (or any successor provision) (a "Separation from Service"). For purposes of Code Section 409A, the right to a series of installment payments under this Agreement shall be treated as a right to a series of separate payments. In no event may the Executive, directly or indirectly, designate the calendar year of a payment. If the termination of employment giving rise to the payments described in Section 3.2.1 is not a Separation from Service, then the amounts otherwise payable pursuant to

Section 3.2.1 will instead be deferred without interest and paid when Executive experiences a Separation from Service. Notwithstanding anything in this Employment Agreement to the contrary or otherwise, with respect to any expense, reimbursement or in-kind benefit provided pursuant to this Employment Agreement that constitutes a "deferral of compensation" within the meaning of Section 409A of the Code and its implementing regulations and guidance, (a) the expenses eligible for reimbursement or in-kind benefits provided to Executive must be incurred during the Employment Term (or applicable survival period), (b) the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive in any other calendar year, (c) the reimbursements for expenses for which Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (d) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit. Notwithstanding any provision to the contrary in this Agreement, if Executive is deemed by Employer at the time of his Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, and if any of the payments due upon Separation From Service set forth herein and/or under any other agreement with Employer are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments will not be provided to Executive prior to the earliest of (i) the expiration of the six (6)-month period measured from the date of Executive's Separation From Service with Employer, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this paragraph will be paid in a lump sum to Executive, and any remaining payments due will be paid as otherwise provided in this Agreement or in the applicable agreement. No interest will be due on any amounts so deferred.

5.13 Dispute Resolution. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Executive's employment with the Employer or out of this Agreement, or the Executive's termination of employment or termination of this Agreement, may not be in the best interests of either the Executive or Employer, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Executive Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided however,* that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the Philadelphia, Pennsylvania metropolitan area. Any award made by such panel shall

be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by Employer. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Executive and Employer. The parties each further agree that the arbitration provisions of this Agreement shall provide each party with its **exclusive remedy**, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury**

[**SIGNATURE PAGE FOLLOWS**]

IN WITNESS WHEREOF, this Employment Agreement has been executed and delivered by the parties hereto as of the Effective Date.

ACLARIS THERAPEUTICS, INC.

By: /s/ Neal Walker	9/17/15
Name: Neal Walker	Date
Title: President & CEO	
/s/ Frank Ruffo	9/17/15
Frank Ruffo	Date

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Exhibit 21.1

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

Exhibit 23.1

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. 333-230614, 333-223922, 333-220149, 333-216703, 333-210379, and 333-207434) of Aclaris Therapeutics, Inc. of our report dated February 25, 2020 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
February 25, 2020

Exhibit 31.1

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 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: February 25, 2020

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

Exhibit 31.2

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 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: February 25, 2020

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

Exhibit 32.1

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, 2019 (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 25th day of February 2020.

/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.