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

FORM 10-K

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

For the fiscal year ended December 31, 2020 **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 has filed a report on and attestation to its management’s assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

As of June 30, 2020, 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 $65.5 million based on the closing price of the registrant’s common stock, as reported by the Nasdaq Global Select Market, on such date.

As of January 31, 2021, 51,804,258 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 2021 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," "can," "will," "to be," "could," "would," "should," "expect," "intend," "plan," "objective," "anticipate," "believe," "estimate," "predict," "project," "potential," "likely," "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 earn revenue from such arrangements;
- our expectations regarding competition;
- our expectations regarding our continued reliance on third parties;
- the impacts of the COVID-19 pandemic on our business;
- our expectations regarding our use of capital; and
- our estimates regarding future revenue, expenses and needs for additional financing.

You should refer to Part I, 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, and you should not place undue reliance on these forward-looking statements. 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 KINect, ESKATA and RHOFADE 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 clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. In addition to developing our novel drug candidates, we are pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our novel drug candidates.

Our Drug Candidates Currently in Development

Our pipeline of drug candidates that we are currently developing is summarized in the table below. These investigational drugs were developed internally utilizing our proprietary KINect drug discovery platform.

Drug Candidate / Program	Target	Route of Administration	Indication	Development Phase
Immuno-Inflammatory Diseases				
ATI-450	MK2 inhibitor	oral	rheumatoid arthritis (moderate to severe)	Phase 2
			additional immuno-inflammatory diseases	Phase 2*
			COVID-19**	Phase 2
ATI-1777	"soft" JAK 1/3 inhibitor	topical	atopic dermatitis (moderate to severe)	Phase 2
ATI-2138	ITK/TXK/JAK3 inhibitor	oral	psoriasis	Pre-IND
			inflammatory bowel disease	
Undisclosed- Gut Restricted Program	JAK1/JAK3 inhibitor	oral	inflammatory bowel disease	Discovery
Undisclosed- Gut Restricted Program	ITK/TXK/JAK3 inhibitor	oral	inflammatory bowel disease	Discovery

* We are currently evaluating additional potential immuno-inflammatory indications which we expect to progress directly into Phase 2.
** This is an investigator-initiated trial sponsored by the University of Kansas Medical Center.

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, including KINect, a proprietary drug discovery platform. This allowed us to bring early-stage research and development activities in-house that we previously outsourced to third parties. We intend to leverage these capabilities and KINect to identify potential drug candidates that we may develop independently or in collaboration with third parties. As part of the Confluence acquisition we also acquired our investigational drug candidates, ATI-450, an inhibitor of the mitogen-activated protein kinase-activated protein kinase 2, or MK2, signaling pathway, and ATI-1777, a topical "soft" Janus kinase, or JAK, inhibitor, as well as several other preclinical drug candidates including inhibitors of interleukin-2-

inducible T cell kinase, or ITK. We also earn revenue from Confluence's provision of contract research services to third parties.

ATI-450, an Investigational Oral MK2 Inhibitor

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 U.S. Food and Drug Administration, or 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 oncology. As an oral drug candidate, we are developing ATI-450 as a potential alternative to injectable anti-TNF/IL1/IL6 biologics and JAK inhibitors for treating certain immuno-inflammatory diseases.

We initiated a Phase 1 single (at 10mg, 30mg, 50mg and 100mg doses) and multiple ascending (at 10mg, 30mg and 50mg doses) dose clinical trial evaluating ATI-450 in 77 healthy subjects in August 2019 (ATI-450-PKPD-101). Final 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) were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain and nausea.

ATI-450 was also evaluated at 80mg and 120mg doses twice daily in a second Phase 1 clinical trial in healthy subjects (ATI-450-PKPD-102). Preliminary topline data from this trial showed that no dose-limiting toxicity was observed. *Ex vivo* analysis of blood samples from this Phase 1 trial also showed that increased cytokine inhibition was achieved with these higher doses of ATI-450. No serious adverse events were reported and all adverse events were mild to moderate. The most common adverse events (reported by 2 or more subjects who received ATI-450) were headache, dizziness, nausea, parasthesia and, in the post-dosing safety follow-up phase of the trial, dry skin. These adverse events were all mild in severity. A final analysis of this trial is underway.

Moderate to Severe Rheumatoid Arthritis

Following the completion of the first Phase 1 clinical trial, in March 2020 we initiated a 12-week, Phase 2a, multicenter, randomized, investigator and patient-blind, sponsor-unblinded, parallel group, placebo-controlled clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-450 in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-201). In the trial, 19 subjects were randomized in a 3:1 ratio (seventeen subjects [15 in the treatment arm and two in the placebo arm] completed treatment) and received either ATI-450 at 50 mg twice daily or placebo, in combination with methotrexate, for 12 weeks. Preliminary topline data from this trial showed that ATI-450 demonstrated durable clinical activity, as defined by a marked and sustained reduction in DAS28-CRP and improvement of ACR20/50/70 responses over 12 weeks. ATI-450 was generally well tolerated. All adverse events were mild to moderate. The most common adverse events (each reported in 2 subjects) were urinary tract infection, or UTI, elevated lipids and ventricular extrasystoles, all of which were determined to be unrelated to treatment except for one UTI. Two subjects withdrew from the trial, one in the treatment arm and one in the placebo arm. The subject in the treatment arm withdrew due to palpitations, which were unrelated to the trial medication, and an elevated creatine phosphokinase, or CPK, which was determined by the site investigator to be treatment-related. The subject in the placebo arm withdrew as a result of prohibited medication needed to treat muscle strain. There was one non-treatment-related serious adverse event (COVID-19) reported in the four-week safety follow-up phase of the trial in a subject who was no longer receiving treatment.

An interim analysis (11 treatment, two placebo) of ex vivo stimulated cytokines from blood samples taken from the treatment arm showed a marked and durable inhibition of TNFα, IL1β, IL6, and IL8 over the 12 week dosing period. Similarly, analysis of endogenous inflammation biomarkers also demonstrated a marked and sustained inhibition of median concentrations of hsCRP, TNFα, IL6, IL8 and MIP1β in the treatment arm over the 12-week period.

We plan to submit for publication a full analysis of the Phase 2a data in a peer-reviewed scientific journal which will include data from other secondary and exploratory endpoints evaluated in the trial, including the four-week safety follow-up data and a full analysis of MRI, pharmacodynamic and pharmacokinetic data. Based on the results observed in the Phase 2a trial, we intend to progress ATI-450 into a Phase 2b trial in moderate to severe rheumatoid arthritis in the second half of 2021.

Cryopyrin-associated Periodic Syndrome

In November 2020, we initiated a Phase 2a multicenter, open-label, single-arm clinical trial to investigate the safety, tolerability, efficacy and pharmacodynamics of ATI-450 for the maintenance of remission in subjects with cryopyrin-associated periodic syndrome, or CAPS, previously managed with anti-IL1 therapy (ATI-450-CAPS-201). Due to the COVID-19 pandemic, subject enrollment in this trial was paused. As a result of the ongoing pandemic and given the positive preliminary topline data from the ATI-450-RA-201 trial, we have decided to focus our efforts and resources on other immuno-inflammatory diseases.

COVID-19

We also supported an investigator-initiated Phase 2a, randomized, double-blind, placebo-controlled clinical trial to investigate the safety and efficacy of ATI-450, when used in addition to standard of care therapy, as a potential treatment for cytokine release syndrome in hospitalized patients with COVID-19. The primary endpoint in this trial is the proportion of subjects who are free from respiratory failure by day 14. We provided funding and clinical drug supply to the University of Kansas Medical Center, the sponsor of the trial. The trial included 20 subjects and is completed. We expect data to be available in the first half of 2021.

ATI-1777, an Investigational Topical "Soft" JAK 1/3 Inhibitor

In June 2020, we submitted an IND for ATI-1777, an investigational topical "soft" JAK 1/3 inhibitor compound, for the treatment of moderate to severe atopic dermatitis. "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.

In October 2020, we initiated a Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to determine the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe atopic dermatitis (ATI-1777-AD-201). We expect data to be available mid-year 2021.

ATI-2138, an Investigational ITJ Inhibitor

We are also developing ATI-2138, an 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 second half of 2021.

Our Other Drug Candidates

We continue to seek third-party partners for our dermatology investigational drug candidate A-101 45% Topical Solution as a potential treatment for common warts (verruca vulgaris).

Manufacturing and Supply

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

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 ATI-450 as a potential treatment for moderate to severe rheumatoid arthritis, there are several different types of therapies in the rheumatoid arthritis market. Medications for the treatment of rheumatoid arthritis currently fall into two categories: drugs that ease symptoms such as nonsteroidal anti-inflammatory drugs and drugs that slow disease activity. Drugs that slow disease activity include corticosteroids and disease-modifying anti-rheumatic drugs, or DMARDs. Disease-modifying drugs include conventional DMARDs such as methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, biologic DMARDs (monoclonal antibodies which inhibit targets such as TNF, IL1, IL6 and costimulatory signaling mechanisms), and targeted synthetic DMARDs such as JAK inhibitors. These types of drugs are produced and sold by large pharmaceutical companies, including AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Merck, Pfizer, and Roche, among others. In addition, we are aware of a number of companies developing and conducting clinical trials for investigational drug candidates, including biosimilars, that, if approved, could compete with ATI-450, if approved, for the treatment of rheumatoid arthritis.

With respect to ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, there are several different types of therapies in the atopic dermatitis market, such as biologics, oral and topical corticosteroids, injectable and oral methotrexate products, oral and topical calcineurin inhibitors, oral mycophenolate products, other JAK inhibitors, other oral antibiotics and antihistamines and phototherapy. There are also several prescription, non-prescription and over-the-counter, or OTC, topical products, including PDE4 inhibitors, utilized to treat atopic dermatitis. These types of drugs are produced and sold by large pharmaceutical companies, including Sanofi and Regeneron Pharmaceuticals, Inc., and Pfizer. In addition, we are aware of a number of companies including large pharmaceutical companies, such as AbbVie, Eli Lilly, Novartis, Incyte, Pfizer and LEO Pharma A/S developing and conducting clinical trials for investigational drug candidates, that, if approved, could compete with ATI-1777, if approved, for the treatment of atopic dermatitis.

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 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, evaluating and taking 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 MK2 signaling pathway inhibitor development program, we own numerous issued patents and pending applications to novel MK2 pathway inhibitors, including our lead candidate ATI-450, and various methods of use that expire, or would expire, between 2031 and 2041, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own two U.S. patents and pending applications in the European Union and other foreign countries directed to ATI-450 and analogs thereof and certain methods of using the same. The U.S. patents expire in 2034 and any claims that may issue from the pending applications expire in 2034, subject to any applicable adjustment or extension. We also own a Patent Cooperation Treaty, or PCT, application directed to deuterated forms of ATI-450 and methods of use, which, if issued, would expire in 2040, subject to any applicable adjustment or extension. Further, we own numerous provisional applications directed to certain methods of using ATI-

450, methods of manufacturing ATI-450 and crystal forms of ATI-450, which, if issued, would each expire in 2041, subject to any applicable adjustment or extension.

With respect to our "soft" JAK inhibitor development program, we own one issued U.S. patent and numerous pending applications in the U.S. and foreign countries to novel "soft" JAK inhibitors and various methods of use that expire, or would expire, between 2038 and 2041, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own one allowed U.S. application and pending applications in the European Union and other foreign countries directed to various novel inhibitors of JAK1 and/or JAK3, including ATI-1777, and methods of using the same, which, if issued, would expire in 2038, subject to any applicable adjustment or extension. We also own two provisional applications directed to topical formulations and crystal forms of ATI-1777, which, if issued, would expire in 2041, subject to any applicable adjustment or extension.

With respect to our ITK inhibitor development program, we own numerous issued U.S. patents and pending applications in the U.S. and foreign countries directed to novel inhibitors of ITK and methods of use that expire, or would expire, between 2035 and 2039, subject to any applicable patent term adjustment or extension that may be available in a particular country. We also own pending U.S., European Union and other foreign country applications directed to ATI-2138 and analogs thereof and methods of using the same, which, if issued, would expire in 2039, subject to any applicable adjustment or extension.

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 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.

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 former 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 closing consideration of $10.3 million in cash and issued 349,527 shares of our common stock with a fair value of $9.7 million to the former Confluence equity holders.

In November 2018, a development milestone specified in the Confluence Agreement was achieved, as a result of which we paid the former Confluence equity holders $2.5 million in cash and issued 253,208 shares of our common stock with a fair value of $2.2 million. Under the Confluence Agreement, 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 to the payments described above, 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 consideration received from such sale, license or transfer in specified circumstances.

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 potential third-party partners that we may consummate a transaction with would seek approval through the New Drug Application, or NDA, pathway.

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 an 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 the 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, and 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 trials 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 NDA 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 filing of the NDA. After the FDA evaluates the NDA and conducts inspections of manufacturing facilities where the drug product and/or its active pharmaceutical ingredient 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 are also 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.

Orphan Drug Designation

Under the Orphan Drug Act, the FDA may grant orphan drug designation to products intended to treat a rare disease or condition—generally one that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting the NDA. After the FDA grants orphan drug designation, the FDA publicly discloses the drug's identity and its intended orphan use. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. The first active moiety to be approved to treat a disease with FDA's orphan drug designation is entitled to a seven-year period of marketing exclusivity in the United States for that product, for that indication. During the seven-year exclusivity period, the FDA may not approve any other applications to market the same drug for the same orphan indication, regardless of patent status, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity or if the FDA finds that the holder of the orphan exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different chemical/biological entity for the same disease or condition. An orphan drug designation also does not preclude the same drug from being developed for a different disease or condition. Among the other benefits of orphan drug designation are tax credits for certain research expenses and a waiver of the application user fee.

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 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 ten 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 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.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, prohibits 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 to the Centers for Medicare & Medicaid Services, or CMS, for covered manufacturers for certain payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Beginning in 2022, applicable manufacturers will also be required to report information regarding payments and other transfers of value provided during the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants, and certified nurse-midwives. 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 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 and their subcontractors that use, disclose, access, or otherwise process protected health information. 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 contain 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 certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several 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 eliminated, 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 eliminated 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". 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 Fifth 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. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the health care reform measures of the Biden administration will impact the Affordable Care Act and our business.

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 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021, 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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30, 2020 providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, the Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also created a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing the President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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. Further, it is also possible that additional governmental action is taken in response to the COVID-19 pandemic. The impact of such actions on our business, if any, cannot presently be determined.

The Hatch Waxman Amendments to the FDCA

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 and Human Capital Resources

As of December 31, 2020, we had 60 total employees, of which 57 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.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

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.

Summary of Risk Factors

- 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 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.
- Our business is dependent on the successful development of our investigational drug candidate, ATI-450.
- We have a limited history as a clinical-stage biopharmaceutical company developing and partnering our drug candidates, which may make it difficult to evaluate the success of our business to date and to assess our future viability.
- 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.
- Our future success depends on our ability to retain key executives and to attract, retain and motivate qualified personnel.
- 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.
- Our business has been adversely impacted and could continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have manufacturing facilities, clinical trial sites or other business operations. The COVID-19 pandemic could adversely affect our operations, including at our headquarters and at our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business.
- If we are unable to obtain and maintain patent protection for our drug candidates, or if the scope of the patent protection obtained is not sufficiently broad, our competitors could develop and commercialize technology and drugs similar or identical to ours, and our ability to successfully pursue strategic alternatives, including identifying and consummating transactions with potential third-party partners, to commercialize our technology and drug candidates may be impaired.
- We face substantial competition, which may result in others discovering, developing or commercializing drugs before or more successfully than we do.

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.

Since inception, we have incurred significant net losses. We incurred net losses of $51.0 million and $161.4 million for the years ended December 31, 2020 and 2019, respectively. As of December 31, 2020, we had an accumulated deficit of $504.5 million. We have financed our operations over the last several years primarily from sales of equity securities and incurring indebtedness in the form of loans from commercial lenders.

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;
- continue the clinical development of ATI-450, our MK2 inhibitor, as a potential treatment for moderate to severe rheumatoid arthritis and potentially other immuno-inflammatory diseases, and ATI-1777, our "soft" JAK inhibitor, as a potential treatment for moderate to severe atopic dermatitis;
- continue to develop our preclinical drug candidates, including ATI-2138, our ITJ inhibitor;
- continue 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 incur 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, 2020, we had cash, cash equivalents and marketable securities of $54.1 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;
- the impact on the timing of our preclinical studies, on the recruitment, enrollment, conduct and timing of our clinical trials, and on our business, due to the COVID-19 pandemic;
- 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 will require additional capital to complete the clinical development of ATI-450 and ATI-1777, 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. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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 as a potential treatment for moderate to severe rheumatoid arthritis and potentially other immuno-inflammatory diseases. The success of our business will significantly depend on our successful development of and/or our ability to pursue strategic alternatives for, 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 potential 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 history as a clinical-stage biopharmaceutical company developing and partnering our drug candidates, which may make it difficult 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. 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 history of being a clinical-stage biopharmaceutical company focused on 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 has been adversely impacted and could continue to be adversely affected by the evolving and ongoing COVID-19 global pandemic in regions where we or third parties on which we rely have manufacturing facilities, clinical trial sites or other business operations. The COVID-19 pandemic could adversely affect our operations, including at our headquarters and at our clinical trial sites, as well as the business or operations of our manufacturers, contract research organizations or other third parties with whom we conduct business.

Our business has been adversely affected by the effects of the COVID-19 pandemic, which has resulted in travel and other restrictions in order to reduce the spread of the disease, which, among other things, direct businesses and governmental agencies to cease non-essential operations at physical locations, prohibit certain non-essential gatherings, and order cessation of non-essential travel. In response to these public health directives and orders, we have implemented a virtual operations strategy, including teleworking and other alternative work arrangements for all employees. The effects of our alternative work arrangement policies may negatively impact productivity, disrupt our business and delay our preclinical drug development and clinical trials and timelines, the magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

Quarantines, executive and similar government orders, and business shutdowns, or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain. Some of our third-party manufacturers which we use for the supply of materials for our drug candidates or other materials necessary to manufacture drug product to conduct preclinical studies and clinical trials are located in countries affected by COVID-19, and should they experience disruptions, such as temporary closures or suspension of services, we would likely experience delays in advancing these studies and trials.

In addition, our clinical trials have been and may continue to be affected by the COVID-19 pandemic. Clinical site initiation and patient enrollment may be delayed due to prioritization of hospital resources toward the COVID-19 pandemic. Some subjects may not be able to comply with clinical trial protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain subjects and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, may adversely impact our clinical trial operations. For example, due to the COVID-19 pandemic subject enrollment in our ATI-450-CAPS-201 trial was paused as a result of which, among other reasons, we have decided to focus our efforts and resources on other immuno-inflammatory diseases.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, the COVID-19 pandemic may be difficult to assess or predict, the widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity and impact our ability to make scheduled payments pursuant to our Loan and Security Agreement with Silicon Valley Bank, or SVB. In addition, a recession or

market correction resulting from the further spread of COVID-19 could materially affect our business and the value of our common stock.

The global COVID-19 pandemic continues to rapidly evolve. The extent to which the COVID-19 pandemic impacts our business, our preclinical and clinical development and our regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted, such as the geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines, stay-at-home orders, social distancing requirements and business closures, and supply chain and other disruptions in the United States and other countries, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease, including the success of mass vaccination efforts. Accordingly, we do not yet know the full extent of the impacts on our business, our preclinical and clinical development and regulatory activities, healthcare systems or the global economy as a whole. However, these impacts could adversely affect our business, financial condition, results of operations and growth prospects.

In addition, to the extent the ongoing COVID-19 pandemic adversely affects our business and results of operations, it may also have the effect of heightening many of the other risks and uncertainties described herein.

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

In March 2020, we entered into the Loan and Security Agreement with SVB, pursuant to which we borrowed $11.0 million. Our obligations under the Loan and Security Agreement are secured by substantially all of our assets except for our intellectual property, and restrict us from encumbering our intellectual property without SVB's prior written consent. The Loan and Security Agreement contains customary representations, warranties and covenants by us, which covenants, among other things, limit our ability, subject to specified exceptions, to convey, sell, lease, transfer, assign or otherwise dispose of our assets; engage in any business other than the businesses currently engaged in by us or reasonably related thereto; liquidate or dissolve; undergo specified change of control events; create, incur, assume or be liable for indebtedness; create, incur, allow or suffer any liens on our property; pay dividends and make other restricted payments; make investments; or enter into any material transactions with our affiliates. Our obligations under the Loan and Security Agreement are subject to acceleration upon the occurrence of specified events of default, including a material adverse change in our business, operations or financial condition. We may also enter into other debt agreements in the future which may contain similar or more restrictive terms.

Our ability to make scheduled monthly payments or to refinance our debt obligations depends on numerous factors, including the amount of our cash reserves and our actual and projected financial and operating performance. These amounts and our performance are subject to certain financial and business factors, as well as prevailing economic and competitive conditions, including the impact of the COVID-19 pandemic, some of which may be beyond our control. We cannot guarantee that we will maintain a level of cash reserves or cash flows from operating activities sufficient to permit us to pay the principal, premium, if any, and interest on our existing or future indebtedness. If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell assets or operations, seek additional capital or restructure or refinance our indebtedness. We cannot guarantee that we would be able to take any of these actions, or that these actions would permit us to meet our scheduled debt service obligations. Failure to comply with the covenants and conditions of the Loan and Security Agreement could result in an event of default, which could result in an acceleration of amounts due under the Loan and Security Agreement. We may not have sufficient funds or may be unable to arrange for additional financing to repay our indebtedness or to make any accelerated payments, and SVB could seek to enforce security interests in the collateral securing such indebtedness, which would harm our business.

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 ATI-450, will depend on several factors, including:

- successful completion of preclinical studies and our clinical trials;
- successful development of manufacturing processes;
- 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, if approved, by a potential third-party partner;
- our potential 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 potential 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 potential third-party partners' ability to compete effectively with other treatment procedures; and
- our potential 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. Following submission, the NDA for any drug candidate may not be 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, which could increase costs and cause delays in the marketing approval process and 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 IRBs 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;
- the COVID-19 pandemic may impact the recruitment, enrollment, conduct and timing of our clinical trials;
- our drug candidates may have undesirable side effects or other unexpected characteristics, causing us or our investigators, regulators or IRBs 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 IRBs 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 IRBs of the institutions in which such trials are being conducted, by a 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, including as a result of factors beyond our control, such as the COVID-19 pandemic. 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 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 increase our costs or necessitate the abandonment or limitation of the development of our drug candidates or 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.

If our drug candidates are associated with side effects in clinical trials or have characteristics that are unexpected, our costs could increase or 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 IRB 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.

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.

Additionally, if we or others identify undesirable side effects caused by our drugs, a number of potentially significant negative consequences could result, including:

- we may need to abandon the development or limit the further development of our drug candidates, including in various populations and for certain indications;
- 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.

For example, we are supporting an investigator-initiated trial of ATI-450 in hospitalized patients with COVID-19. Although the COVID-19 trial is not sponsored by us, the use of ATI-450 in a hospitalized and severely ill patient population may be associated with adverse events and risks that could jeopardize our development of ATI-450 in other populations and indications, including our trials in subjects with moderate to severe rheumatoid arthritis.

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.

Interim, topline and preliminary data from our clinical trials that we announce or publish from time to time may change as more subject data become available and are subject to audit and verification procedures that could result in material changes in the final data.

From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials, such as the preliminary topline results from our Phase 2a trial of ATI-450 in subjects with moderate to severe rheumatoid arthritis, which are based on a preliminary analysis of then-available data, and the results and related findings and conclusions are subject to change following a full analysis of all data related to the particular trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. In addition, we may report preliminary analyses of only certain endpoints rather than all endpoints. As a result, the interim, topline or preliminary results that we report may differ from future results of the same trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim, topline and preliminary data should be viewed with caution until the final data are available. We may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as subject enrollment continues and more subject data become available. Adverse differences between interim, topline or preliminary data and final data could significantly harm our reputation and business prospects. Further, disclosure of interim, topline or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the potential of the particular program, the likelihood of marketing approval or commercialization of the particular drug candidate, any approved product, and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is derived from information that is typically extensive, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any

information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular program, drug candidate or our business.

If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, 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 may be harmed, which could harm our business, operating results, prospects or financial condition.

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 develop, 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 moderate to severe rheumatoid arthritis and potentially other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis. 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 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 potential 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 potential third-party partners may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If such 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 potential 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 ATI-450 as a potential treatment for moderate to severe rheumatoid arthritis, there are several different types of therapies in the rheumatoid arthritis market. Medications for the treatment of rheumatoid arthritis currently fall into two categories: drugs that ease symptoms such as nonsteroidal anti-inflammatory drugs and drugs that slow disease activity. Drugs that slow disease activity include corticosteroids and DMARDs. Disease-modifying drugs include conventional DMARDs such as methotrexate, sulfasalazine, leflunomide, hydroxychloroquine, biologic DMARDs (monoclonal antibodies which inhibit targets such as TNF, IL1, IL6 and costimulatory signaling mechanisms), and targeted synthetic DMARDs such as JAK inhibitors. These types of drugs are produced and sold by large pharmaceutical companies, including AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Merck, Pfizer, and Roche, among others. In addition, we are aware of a number of companies developing and conducting clinical trials for investigational drug candidates, including biosimilars, that, if approved, could compete with ATI-450, if approved, for the treatment of rheumatoid arthritis.

With respect to ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, there are several different types of therapies in the atopic dermatitis market, such as biologics, oral and topical corticosteroids, injectable and oral methotrexate products, oral and topical calcineurin inhibitors, oral mycophenolate products, other JAK inhibitors, other oral antibiotics and antihistamines and phototherapy. There are also several prescription, non-prescription and OTC topical products, including PDE4 inhibitors, utilized to treat atopic dermatitis. These types of drugs are produced and sold by large pharmaceutical companies, including Sanofi and Regeneron Pharmaceuticals, Inc., and Pfizer. In addition, we are aware of a number of companies including large pharmaceutical companies, such as AbbVie, Eli Lilly, Novartis, Incyte, Pfizer and LEO Pharma A/S developing and conducting clinical trials for investigational drug candidates, that, if approved, could compete with ATI-1777, if approved, for the treatment of atopic dermatitis.

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 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 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 these 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, if approved, 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 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 drug 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. 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 comparable foreign 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 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. 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. We intend to partner with pharmaceutical and biotechnology companies for the further development and/or commercialization of our 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.

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.

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. Our issued patent covering other novel “soft” JAK inhibitors expires 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. 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.

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

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

We 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, our lead inhibitor of the MK2 signaling pathway, ATI-450, is currently covered by patents and applications in the United States, European Union and other 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, rather we have pending applications in the United States, European Union and other foreign markets directed to each of ATI-1777 and ATI-2138.

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. 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, and even if they are able to, it may result in the reduction of revenue we earn from such partner as a result of payment obligations such partner has to the licensor.

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 potential third-party partners may not be able to obtain any required license on commercially reasonable terms or at all. Even if we or our potential 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 potential 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 potential 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 potential 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 potential 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.

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, which would harm 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, and earn revenue from such arrangements. In addition, any such challenge on any divested product could harm our ability to earn revenue from the arrangements for such product.

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. Our issued patent covering other novel "soft" JAK inhibitors expires 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. 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 such an event, we may need to negotiate a settlement agreement with such third party over the use of our trademarks, which we may not be able to do on commercially reasonable terms, if at all. 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:

- we, our licensors or any potential 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 potential 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, other regulatory agencies in the United States 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 outside the United States, 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, if approved, are marketed internationally by our potential third-party partners, 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 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. Physicians, on the other hand, may prescribe products for off-label uses. Although the FDA and other regulatory agencies do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, they do restrict promotional communications from companies or their sales force with respect to off-

label uses of products for which marketing clearance has not been issued. However, companies may share truthful and not misleading information that is otherwise consistent with the product's FDA approved labeling. 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 and their subcontractors that use, disclose, access, or otherwise process protected health information, 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, and, beginning in 2022, will require applicable manufacturers to report information related to payments and other transfers of value provided in the previous year to physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives. 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 certain aspects of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, several 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 eliminated, 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 eliminated 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". 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 Fifth 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. The U.S. Supreme Court is currently reviewing the case, although it is unknown when a decision will be made. Further, although the U.S. Supreme Court has not yet ruled on the constitutionality of the Affordable Care Act, on January 28, 2021, President Biden issued an executive order to initiate a special enrollment period from February 15, 2021 through May 15, 2021 for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the Affordable Care Act. It is unclear how the Supreme Court ruling, other such litigation, and the health care reform measures of the Biden administration will impact the Affordable Care Act and 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 2030 with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 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. Further, it is also possible that additional governmental action is taken in response to the COVID-19 pandemic.

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 used several means to propose or implement drug pricing reform, including through federal budget proposals, executive orders and policy initiatives. For example, on July 24, 2020 and September 13, 2020, President Trump announced several executive orders related to prescription drug pricing that seek to implement several of the administration's proposals. As a result, the FDA released a final rule on September 24, 2020, effective November 30,

2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a new safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed pending review by the Biden administration until March 22, 2021. On November 20, 2020, CMS issued an interim final rule implementing President Trump's Most Favored Nation executive order, which would tie Medicare Part B payments for certain physician-administered drugs to the lowest price paid in other economically advanced countries, effective January 1, 2021. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. It is unclear whether the Biden administration will work to reverse these measures or pursue similar policy initiatives. 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.

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 potential 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, if approved, 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 have commitments under employment, 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

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;
- the evolution of the COVID-19 pandemic and success of mass vaccination efforts; 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 indemnification 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.

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.

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 a "smaller reporting company" and, as a result of the reduced disclosure and governance requirements applicable to smaller reporting companies, our common stock may be less attractive to investors.

We are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not smaller reporting companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting; and
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements.

We may take advantage of these reporting exemptions until we are no longer a smaller reporting company. We will remain a smaller reporting company until the last day of any fiscal year for so long as either (1) the market value of our shares of common stock held by non-affiliates does not equal or exceed $250.0 million as of the prior June 30th, or (2) our annual revenues did not equal or exceed $100.0 million during such completed fiscal year and the market value of our shares of common stock held by non-affiliates did not equal or exceed $700.0 million as of the prior June 30th.

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.

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

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and the rules and regulations of the stock market on which our common stock is listed. The Sarbanes-Oxley Act requires, among other

things, that we maintain effective disclosure controls and procedures and internal control over financial reporting, and perform system and process evaluation and testing of our internal control over financial reporting to allow management to report on the effectiveness of our internal control over financial reporting. This requires that we incur substantial additional professional fees and internal costs to expand our accounting and finance functions and that we expend significant management efforts.

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

If we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements, and we may conclude that our internal control over financial reporting is not effective. If that were to happen, the market price of our stock could decline, and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC, or other regulatory authorities.

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

As of December 31, 2020, we had federal and state net operating loss carryforwards, or NOLs, of $367.6 million and $369.6 million, respectively, which will begin to expire in 2032. Under the 2017 Tax Act, as modified by the Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, federal NOL carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but, in the case of tax years beginning after 2020, may only be used to offset 80% of our taxable income annually. Federal NOL carryforwards generated in taxable years beginning in 2018, 2019 and 2020 will similarly carry forward indefinitely but will not be subject to such 80% of annual taxable income limitation. It is uncertain if and to what extent various states will conform to the federal tax law. As of December 31, 2020, we also had federal research and development tax credit carryforwards of $8.6 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. We also have $0.2 million of loss carryforwards in the United Kingdom which can be carried forward indefinitely. 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 July 20, 2020. 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 after July 20, 2020. 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.

Exclusive forum provisions in our amended and restated certificate of incorporation and amended and restated bylaws could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or other 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. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated bylaws provide the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions.

Our amended and restated certificate of incorporation and amended and restated bylaws further provide any person or entity purchasing or otherwise acquiring any interest in shares of our common stock is deemed to have notice of and consented to the foregoing provisions. These exclusive forum provisions 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 lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive-forum provision to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

General Risk Factors

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.

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.

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.

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 (as modified by the CARES 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 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 a “smaller reporting 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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

We sublease 33,019 square feet of space for our headquarters in Wayne, Pennsylvania, which we use for our therapeutics business. The sublease has a term through October 2023. If for any reason the master lease is terminated or expires prior to October 2023, our sublease will automatically terminate.

We also sublease 20,433 square feet of office and laboratory space in St. Louis, Missouri, which we use for our therapeutics and contract research businesses. The sublease has an initial term through June 2029. We have the option to extend the initial term for two additional five-year periods.

We believe that our facilities are suitable and adequate to meet our current needs.

Item 3. Legal Proceedings

From time to time we are subject to litigation and claims arising in the ordinary course of business including intellectual property and product liability litigation, but, except as stated below, we are not currently a party to any material legal proceedings and we are not aware of any other 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.

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 (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, our non-marketed FDA-approved product, 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 filed a motion to dismiss the consolidated amended complaint on April 17, 2020. Fulcher filed an opposition to the defendants’ motion on June 15, 2020, and the defendants filed a reply to such opposition on August 4, 2020. Oral argument on the pending motion to dismiss is scheduled for February 25, 2021. The motion remains under judicial consideration.

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' then-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.

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 January 31, 2021, we had 51,804,258 shares of common stock outstanding held by 56 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 Part I, Item 1A. "Risk Factors," and "Special Note Regarding Forward-Looking Statements."

Overview

We are a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. In addition to developing our novel drug candidates, we are pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our novel drug candidates.

ATI-450, an Investigational Oral MK2 Inhibitor

We submitted an Investigational New Drug Application, or IND, in April 2019 for ATI-450, an investigational oral, novel, small molecule selective mitogen-activated protein kinase-activated protein kinase 2, or MK2, inhibitor compound, for the treatment of rheumatoid arthritis, which was allowed by the U.S. Food and Drug Administration, or 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 oncology. As an oral drug candidate, we are developing ATI-450 as a potential alternative to injectable anti-TNF/IL1/IL6 biologics and JAK inhibitors for treating certain immuno-inflammatory diseases.

We initiated a Phase 1 single (at 10mg, 30mg, 50mg and 100mg doses) and multiple ascending (at 10mg, 30mg and 50mg doses) dose clinical trial evaluating ATI-450 in 77 healthy subjects in August 2019 (ATI-450-PKPD-101). Final 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) were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain and nausea.

ATI-450 was also evaluated at 80mg and 120mg doses twice daily in a second Phase 1 clinical trial in healthy subjects (ATI-450-PKPD-102). Preliminary topline data from this trial showed that no dose-limiting toxicity was observed. Ex vivo analysis of blood samples from this Phase 1 trial showed that increased cytokine inhibition was achieved with these higher doses of ATI-450. No serious adverse events were reported and all adverse events were mild to moderate. The most common adverse events (reported by 2 or more subjects who received ATI-450) were headache, dizziness, nausea, parasthesia and, in the post-dosing safety follow-up phase of the trial, dry skin. These adverse events were all mild in severity. A final analysis of this trial is underway.

Moderate to Severe Rheumatoid Arthritis

Following the completion of the first Phase 1 clinical trial, in March 2020 we initiated a 12-week, Phase 2a, multicenter, randomized, investigator and patient-blind, sponsor-unblinded, parallel group, placebo-controlled clinical trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-450 in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-201). In the trial, 19 subjects were randomized in a 3:1 ratio (seventeen subjects [15 in the treatment arm and two in the placebo arm] completed treatment) and received either ATI-450 at 50 mg twice daily or placebo, in combination with methotrexate, for 12 weeks. Preliminary topline data from this trial showed that ATI-450 demonstrated durable clinical activity, as defined by a marked and sustained reduction in DAS28-CRP and improvement of ACR20/50/70 responses over 12 weeks. ATI-450 was generally well tolerated. All adverse events were mild to moderate. The most common adverse events (each reported in 2 subjects) were urinary tract infection, or UTI, elevated lipids and ventricular extrasystoles, all of which were determined to be unrelated to treatment except for one UTI. Two subjects withdrew from the trial, one in the treatment arm and one in the placebo arm. The subject in the treatment arm withdrew due to palpitations, which were unrelated to the trial medication, and an elevated creatine phosphokinase,

or CPK, which was determined by the site investigator to be treatment-related. The subject in the placebo arm withdrew as a result of prohibited medication needed to treat muscle strain. There was one non-treatment-related serious adverse event (COVID-19) reported in the four-week safety follow-up phase of the trial in a subject who was no longer receiving treatment.

An interim analysis (11 treatment, two placebo) of ex vivo stimulated cytokines from blood samples taken from the treatment arm showed a marked and durable inhibition of TNFα, IL1β, IL6, and IL8 over the 12 week dosing period. Similarly, analysis of endogenous inflammation biomarkers also demonstrated a marked and sustained inhibition of median concentrations of hsCRP, TNFα, IL6, IL8 and MIP1β in the treatment arm over the 12-week period.

We plan to submit for publication a full analysis of the Phase 2a data in a peer-reviewed scientific journal which will include data from other secondary and exploratory endpoints evaluated in the trial, including the four-week safety follow-up data and a full analysis of MRI, pharmacodynamic and pharmacokinetic data. Based on the results observed in the Phase 2a trial, we intend to progress ATI-450 into a Phase 2b trial in moderate to severe rheumatoid arthritis in the second half of 2021.

Cryopyrin-associated Periodic Syndrome

In November 2020, we initiated a Phase 2a multicenter, open-label, single-arm clinical trial to investigate the safety, tolerability, efficacy and pharmacodynamics of ATI-450 for the maintenance of remission in subjects with cryopyrin-associated periodic syndrome, or CAPS, previously managed with anti-IL1 therapy (ATI-450-CAPS-201). Due to the COVID-19 pandemic, subject enrollment in this trial was paused. As a result of the ongoing pandemic and given the positive preliminary topline data from the ATI-450-RA-201 trial, we have decided to focus our efforts and resources on other immuno-inflammatory diseases.

ATI-1777, an Investigational Topical "Soft" JAK 1/3 Inhibitor

In June 2020, we submitted an IND for ATI-1777, an investigational topical "soft" JAK 1/3 inhibitor compound, for the treatment of moderate to severe atopic dermatitis. "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.

In October 2020, we initiated a Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to determine the efficacy, safety, tolerability and pharmacokinetics of ATI-1777 in subjects with moderate to severe atopic dermatitis (ATI-1777-AD-201). We expect data to be available mid-year 2021.

ATI-2138, an Investigational ITJ Inhibitor

We are also developing ATI-2138, an 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 second half of 2021.

Our Other Drug Candidates

We continue to seek third-party partners for our dermatology investigational drug candidate A-101 45% Topical Solution as a potential treatment for common warts (verruca vulgaris).

Financial Overview

Since our inception, we have incurred significant operating losses. Our net loss was $51.0 million for the year ended December 31, 2020 and $161.4 million for the year ended December 31, 2019. As of December 31, 2020, we had an accumulated deficit of $504.5 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. 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 equity securities and incurring indebtedness in the form of loans from commercial lenders. In the near term, we expect to finance our operations through these and 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.

Recent Developments

January 2021 Public Offering

In January 2021, we closed a public offering in which we sold 6,306,271 shares of common stock at a price to the public of $17.50 per share, for aggregate gross proceeds of $110.4 million. We paid underwriting discounts and commissions of $6.6 million, and also 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 $103.5 million.

Impact of COVID-19 on Our Business

The impacts of the global COVID-19 pandemic continue to evolve. We have implemented a virtual operations strategy, including teleworking and other alternative work arrangements for our employees, intended to protect the health and safety of our employees while enabling us to continue to develop our drug candidates and provide contract research services to our clients. We are focused on ensuring the continuity of our operations. However, COVID-19 has caused disruptions to our business. For example, due to the COVID-19 pandemic subject enrollment in our ATI-450-CAPS-201 trial was paused as a result of which, among other reasons, we have decided to focus our efforts and resources on other immuno-inflammatory diseases.

If COVID-19 continues to spread, we may experience additional disruptions that could severely impact our business, results of operations and prospects, including the timing of our development programs and our clinical trials, including our trials of ATI-450 as a potential treatment for moderate to severe rheumatoid arthritis and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis. The extent to which the COVID-19 pandemic impacts our business, our preclinical and clinical development and our regulatory efforts will depend on future developments that are highly uncertain and cannot be predicted, such as the geographic spread of the disease, the duration of the outbreak, travel restrictions, quarantines, stay-at-home orders, social distancing requirements, business closures and supply chain and other disruptions in the United States and other countries, and the effectiveness of actions taken in the United States and other countries to contain and treat the disease, including the administration of vaccines. Accordingly, we do not yet know the full extent of the potential impacts on our business, our preclinical and clinical development and regulatory activities.

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 Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.), or 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 closing consideration of $10.3 million in cash and issued 349,527 shares of our common stock with a fair value of $9.7 million to the former Confluence equity holders.

In November 2018, a development milestone specified in the Confluence Agreement was achieved, as a result of which we paid the former Confluence equity holders $2.5 million in cash and issued 253,208 shares of our common stock with a fair value of $2.2 million. Under the Confluence Agreement, 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 to the payments described above, 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 consideration received from such sale, license or transfer in specified circumstances.

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 (oxymetazoline hydrochloride) cream, 1%, or 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 certain agreements with third parties.

Asset Purchase Agreement with Allergan

In November 2018, we acquired 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.

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 (hydrogen peroxide) topical solution, 40% (w/w), or ESKATA, our non-marketed FDA-approved product, 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 is presented in 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. There are 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 clinical trial sites and consultants that conduct our clinical trials and preclinical studies, and investigator-initiated trials;
- 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;
- 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 related to the revaluation 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 moderate to severe rheumatoid arthritis and potentially other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, continue the development of our preclinical compounds, and continue to discover and develop additional drug candidates. We expense research and development costs as incurred. Our direct research and development expenses primarily consist of external costs including fees paid to CROs, consultants, investigator sites, regulatory agencies and third parties that manufacture our preclinical and clinical trial materials, and are tracked on a program-by-program basis. We do not allocate personnel costs, facilities or other indirect expenses, to specific research and development programs.

The successful development of our drug candidates is highly uncertain. 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 impact on the recruitment, enrollment, conduct and timing of our clinical trials due to the COVID-19 pandemic;
- 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 or other development activities. We may elect to discontinue, delay or modify the development, including 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.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and related costs, including stock-based compensation, for personnel in executive, administrative, finance and legal functions. General and administrative expenses also include facility-related costs, patent filing and prosecution costs, professional fees for legal, auditing and tax services, investor relations costs, insurance costs, travel expenses, as well as a milestone payment under a third party agreement.

Other Income (Expense), net

Other income (expense), net primarily consists of interest earned on our cash, cash equivalents and marketable securities, interest expense related to our debt obligations, 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.

Product sales, net is presented in discontinued operations for all periods presented.

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 and as such, recognize revenue in the amount which we have the right to invoice. ASC Topic 606 also provides an optional exemption, which we have elected to apply, from disclosing remaining performance obligations when revenue is recognized from the satisfaction of the performance obligation in accordance with the "right to invoice" practical expedient.

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.

Intangible Assets

Our intangible assets include both definite-lived and indefinite-lived assets. Our definite-lived intangible assets consist of a drug discovery platform acquired through the acquisition of Confluence, and prior to the disposition in 2019, also included the intellectual property rights related to RHOFADE. 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 indefinite-lived intangible assets consist of an in-process research and development, or IPR&D, drug candidate also 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 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. The impairment test is a qualitative assessment based upon the then current facts and circumstances related to operations of the reporting unit. 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 a 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.

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 a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon the achievement of certain development, regulatory and commercial milestones, as well as future projected sales performance, at its estimated fair value on the date of acquisition. The ultimate amount of future payments, if any, is based on criteria such as sales performance and the achievement of certain regulatory and sales milestones. We estimate the fair value of the contingent consideration liability related to the achievement of regulatory milestones by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a credit-risk-adjusted interest rate. We estimate the fair value of the contingent consideration liability associated with sales milestones and royalties by estimating future sales levels, assigning an achievement probability and discounting the associated cash payment amounts to their present values using a risk-adjusted rate of return. Significant assumptions used in our estimates include the probability of success of both achieving regulatory milestones and commencing commercialization, which are based upon an asset's current stage of development and ranged between 4% and 15%. We evaluate fair value estimates of contingent consideration liabilities on a quarterly basis. Any change in fair value reflects 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 candidate, 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, 2020, we updated our assumptions for contingent consideration related to the acquisition of Confluence as a result of the successful completion of a Phase 1 clinical trial for ATI-450 and the submission and allowance of an IND for ATI-1777, which resulted in a charge of $2.4 million. 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 submission and allowance 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 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.

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.

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, 2020 and 2019

(In thousands)	Year Ended December 31, 2020	2019	Change
Revenues:			
Contract research	$ 5,786	$ 4,227	$ 1,559
Other revenue	696	—	696
Total revenue	6,482	4,227	2,255
Costs and expenses:			
Cost of revenue	5,133	4,055	1,078
Research and development	31,731	64,899	(33,168)
General and administrative	20,530	27,827	(7,297)
Goodwill impairment	—	18,504	(18,504)
Total costs and expenses	57,394	115,285	(57,891)
Loss from operations	(50,912)	(111,058)	60,146
Other expense, net	(424)	(2,484)	2,060
Loss from continuing operations before income taxes	(51,336)	(113,542)	62,206
Income tax benefit	(182)	—	(182)
Loss from continuing operations	(51,154)	(113,542)	62,388
Income (loss) from discontinued operations, net of tax	139	(47,812)	47,951
Net loss	$ (51,015)	$ (161,354)	$ 110,339

Revenue

Contract research revenue was $5.8 million and $4.2 million for the years ended December 31, 2020 and 2019, respectively, and was comprised primarily of fees earned from the provision of laboratory services to our clients through Confluence. Other revenue for the year ended December 31, 2020 consisted of $0.7 million of royalties earned on net sales of RHOFADE pursuant to the asset purchase agreement with EPI Health.

Cost of Revenue

Cost of revenue was $5.1 million and $4.1 million for the years ended December 31, 2020 and 2019, respectively, and related to providing laboratory services to our clients through Confluence. The increase in cost of revenue was driven primarily by increased personnel and lab supply costs as well as an increase in overhead expenses.

Research and Development Expenses

The following table summarizes our research and development expenses:

(In thousands)	Year Ended December 31, 2020	2019	Change
ATI-450	$ 8,268	$ 7,839	$ 429
ATI-1777	3,993	3,612	381
ATI-2138	2,412	1,771	641
Other JAK inhibitors	265	11,102	(10,837)
A-101 45% Topical Solution	611	13,309	(12,698)
Discovery	2,141	4,152	(2,011)
Other research and development	1,564	2,177	(613)
Personnel	7,165	9,612	(2,447)
Stock-based compensation	2,919	5,091	(2,172)
Milestones and licensing	—	5,500	(5,500)
Contingent consideration	2,393	734	1,659
Total research and development expenses	$ 31,731	$ 64,899	$ (33,168)

ATI-450

Research and development expenses for ATI-450 during the year ended December 31, 2020 primarily consisted of costs associated with multiple clinical trials, including a Phase 2a trial in subjects with moderate to severe rheumatoid arthritis. ATI-450 expenses during the year ended December 31, 2019 primarily consisted of preclinical development activities and activities related to a Phase 1 clinical trial that was completed in January 2020. ATI-450 expenses increased during the year ended December 31, 2020 due to an increase in costs associated with various ongoing clinical trials, partially offset by lower preclinical development activities.

ATI-1777

Expenses for ATI-1777 were higher during the year ended December 31, 2020 primarily due to costs associated with a Phase 2a clinical trial in subjects with moderate to severe atopic dermatitis which commenced in 2020, partially offset by lower preclinical development activities.

ATI-2138

Expenses for ATI-2138 were higher during the year ended December 31, 2020 primarily due to preclinical development activities and IND-enabling studies.

Other JAK inhibitors

The decrease in expenses related to other JAK inhibitors primarily resulted from lower expenses in the year ended December 31, 2020 following the completion of multiple Phase 2 clinical trials of our legacy JAK inhibitors, ATI-501 and ATI-502, in 2019.

A-101 45% Topical Solution

Expenses related to A-101 45% Topical Solution decreased primarily due to lower expenses in the year ended December 31, 2020 following the completion of our Phase 3 clinical trials in 2019.

Discovery and other research and development

Research and development expenses related to discovery decreased during the year ended December 31, 2020 as our discovery-stage assets matured to clinical-stage assets. As a result of this transition, we focused fewer resources on our discovery-stage assets in 2020 compared to 2019. Other research and development expenses, which primarily included expenses for medical affairs activities, were lower primarily due to a decrease in activities for our A-101 45% Topical

Solution, ATI-501 and ATI-502 clinical trials that were completed in 2019. Additionally, travel expenses were lower during the year ended December 31, 2020 due to the COVID-19 pandemic.

Personnel and stock-based compensation

Personnel expenses and stock-based compensation decreased due to lower headcount primarily resulting from the restructuring announced in September 2019.

Milestones and licensing and contingent consideration

In 2019, we recorded $5.5 million of expenses for payments under a license agreement upon the achievement of a development milestone and a fee related to a contract amendment. The change in contingent consideration during the year ended December 31, 2020 was the result of updates to our assumptions as a result of the completion of a successful Phase 1 clinical trial for ATI-450 and the submission and allowance of an IND for ATI-1777, while the change in contingent consideration during the year ended December 31, 2019 was the result of updates to our assumptions as a result of the submission and allowance of an IND for ATI-450.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

	Year Ended December 31,		
(In thousands)	**2020**	**2019**	**Change**
Personnel	$ 5,671	$ 8,342	$ (2,671)
Professional and legal fees	3,671	3,995	(324)
Facility and support services	1,743	2,574	(831)
Other general and administrative	2,103	2,628	(525)
Stock-based compensation	7,342	10,288	(2,946)
Total general and administrative expenses	$ 20,530	$ 27,827	$ (7,297)

Personnel and stock-based compensation expenses decreased due to lower headcount primarily resulting from the restructuring announced in September 2019. Professional and legal fees included accounting, legal, investor relations and corporate communication costs, as well as legal fees related to patents and current lawsuits described in this report. Professional and legal fees were lower year-over-year primarily due to lower corporate legal fees. Facility and support services included general office expenses, information technology costs and other expenses, and decreased primarily due to lower operational and other overhead costs. Other general and administrative expenses was lower primarily due to reduced travel-related activities in light of the COVID-19 pandemic.

Goodwill Impairment

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

Other Expense, net

The $2.1 million decrease in other expense, net was primarily due to lower interest expense and fees associated with outstanding debt balances.

Loss from Discontinued Operations

The decrease in loss from discontinued operations was due to the divestiture of RHOFADE (see Note 3 to the consolidated financial statements included in this report for additional information). We recorded income from discontinued operations of $0.1 million during the year ended December 31, 2020 which consisted of $0.4 million of RHOFADE product sales due to a reversal of previously accrued product sales-related reserves, partially offset by $0.3 million of expenses.

Comparison of Years Ended December 31, 2019 and 2018

(In thousands)	Year Ended December 31, 2019	2018	Change
Revenues:			
Contract research	$ 4,227	$ 4,651	$ (424)
Other revenue	—	1,500	(1,500)
Total revenue	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
General and administrative	27,827	25,761	2,066
Goodwill impairment	18,504	—	18,504
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 before income taxes	(113,542)	(82,104)	(31,438)
Income tax benefit	—	—	—
Loss from continuing operations	(113,542)	(82,104)	(31,438)
Loss from discontinued operations, net of tax	(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 our clients through Confluence. Other revenue for the year ended December 31, 2018 related to payments associated with a license agreement and consisted of an upfront payment of $1.0 million and $0.5 million earned upon the achievement of a specified regulatory milestone.

Cost of Revenue

Cost of revenue was $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.

Research and Development Expenses

The following table summarizes our research and development expenses:

(In thousands)	Year Ended December 31, 2019	2018	Change
ATI-450	$ 7,839	$ 4,068	$ 3,771
ATI-1777	3,612	8	3,604
ATI-2138	1,771	—	1,771
Other JAK inhibitors	11,102	22,449	(11,347)
A-101 45% Topical Solution	13,309	10,114	3,195
Discovery	4,152	4,082	70
Other research and development	2,177	4,035	(1,858)
Personnel	9,612	8,332	1,280
Stock-based compensation	5,091	6,481	(1,390)
Milestones and licensing	5,500	—	5,500
Contingent consideration	734	1,272	(538)
Total research and development expenses	$ 64,899	$ 60,841	$ 4,058

ATI-450

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.

ATI-1777

Expenses related to ATI-1777 increased during the year ended December 31, 2019 due to higher preclinical activities and IND-enabling preclinical studies.

ATI-2138

Expenses for ATI-2138 were higher during the year ended December 31, 2019 primarily due to preclinical development activities.

Other JAK inhibitors

Development expenses related to other JAK inhibitors decreased primarily due to lower expenses in the year ended December 31, 2019 following the completion of multiple Phase 2 clinical trials of ATI-501 and ATI-502 in 2019.

A-101 45% Topical Solution

Expenses related to A-101 45% Topical Solution increased primarily due to higher expenses associated with our two pivotal Phase 3 clinical trials, which were initiated during 2018 and were completed in 2019.

Discovery and other research and development

Discovery expenses were consistent year-over-year and reflected our efforts to progress various programs to candidate selection and clinical-stage. The decrease in other research and development expenses was primarily due to lower costs related to legacy dermatology assets and lower travel expenses.

Personnel and stock-based compensation

The increase in personnel expenses, which includes restructuring expenses, was primarily the result of increased headcount prior to our restructuring in 2019. Restructuring expenses primarily included the cost of termination benefits

given to employees that were involuntarily terminated during the year ended December 31, 2019. The decrease in stock-based compensation expense was primarily the result of forfeitures by certain employees during 2019.

Milestones and licensing and contingent consideration

In 2019, we recorded $5.5 million of expenses for payments under a license agreement upon the achievement of a development milestone and a fee related to a contract amendment. The change in contingent consideration during the year ended December 31, 2019 was the result of updates to our assumptions as a result of the submission and allowance of an IND for ATI-450. The change in contingent consideration during the year ended December 31, 2018 was the result of updates to our assumptions related to ATI-1777 that reflected the achievement of a specified development milestone in November 2018 under the Confluence Agreement.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

(In thousands)	Year Ended December 31, 2019	2018	Change
Personnel	$ 8,342	$ 7,006	$ 1,336
Professional and legal fees	3,995	5,091	(1,096)
Facility and support services	2,574	2,349	225
Other general and administrative	2,628	1,998	630
Stock-based compensation	10,288	9,317	971
Total general and administrative expenses	$ 27,827	$ 25,761	$ 2,066

Personnel expenses, which includes restructuring expenses, and stock-based compensation expenses increased due to higher 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 in 2019, as well as higher 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 a decline in our stock price. Our impairment analysis noted that the fair value for the therapeutics reporting unit was less than its carrying value. As a result, we recorded an impairment charge of $18.5 million.

Other Income (Expense), net

The $5.2 million decrease in other income (expense), net was primarily due to higher interest expense incurred on outstanding debt balances.

Loss from Discontinued Operations

In September 2019, we announced the completion of a strategic review and our decision to refocus on our immuno-inflammatory development programs and to actively seek partners for our commercial products. The decrease in loss from discontinued operations was driven by higher product sales, net partially offset by higher expenses (see Note 18 to the consolidated financial statements included in this report for additional information).

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 financings. 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 potential third-party partners to further develop, obtain marketing approval for and/or commercialize our drug candidates, we may receive upfront payments, milestone payments or royalties from such arrangements that would increase our liquidity.

As of December 31, 2020, we had cash, cash equivalents and marketable securities of $54.1 million. Subsequent to December 31, 2020, we raised net proceeds of $103.5 million through a public offering of common stock. 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, other than our term loan facility, lease obligations, and contingent obligations under the Confluence Agreement, which is summarized above under “Overview—Acquisition and License Agreements.”

Equity Financing

January 2021 Public Offering

In January 2021, we closed a public offering in which we sold 6,306,271 shares of common stock at a price to the public of $17.50 per share, for aggregate gross proceeds of $110.4 million. We paid underwriting discounts and commissions of $6.6 million, and we also 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 $103.5 million.

Equity Purchase Agreement with Lincoln Park Capital Fund, LLC

In August 2020, we entered into a purchase agreement, or the Purchase Agreement, with Lincoln Park. The Purchase Agreement provided that, upon the terms and subject to the conditions and limitations set forth therein, we could sell to Lincoln Park, at our discretion, up to $15.0 million of shares of our common stock over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, we issued 121,584 shares of our common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of our common stock on the effective date of the Purchase Agreement resulting in an aggregate fair value of $0.3 million. Through December 31, 2020, we sold 2,111,170 shares of our common stock to Lincoln Park under the Purchase Agreement for net proceeds of $7.7 million. We did not sell any additional shares prior to terminating the Purchase Agreement in January 2021 in connection with the public offering of common stock described above.

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.

Debt Financing

Loan and Security Agreement with Silicon Valley Bank

In March 2020, we entered into a Loan and Security Agreement with SVB. The Loan and Security Agreement provides for $11.0 million in term loans, of which we borrowed the entire amount on March 30, 2020. The Loan and Security Agreement is secured by substantially all of our assets other than intellectual property.

The term loan repayment schedule provides for interest only payments beginning April 1, 2020 and continuing through March 1, 2022, followed by 24 consecutive equal monthly installments of principal, plus monthly payments of accrued interest, starting on April 1, 2022 and continuing through the maturity date of March 1, 2024. All outstanding principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan and Security Agreement provides for an annual interest rate equal to the greater of (i) the prime rate then in effect as reported in The Wall Street Journal plus 2% and (ii) 6.75%.

The Loan and Security Agreement includes a final payment fee equal to 5% of the original principal amount borrowed. We have the option to prepay the outstanding balance of the term loans in full, subject to a prepayment premium of (i) 3% of the original principal amount borrowed for any prepayment on or prior to the first anniversary of March 30, 2020, (ii) 2% of the original principal amount borrowed for any prepayment after the first anniversary and on or before the second anniversary of March 30, 2020 or (iii) 1% of the original principal amount borrowed for any prepayment after the second anniversary of March 30, 2020 but before March 1, 2024.

The Loan and Security Agreement contains a customary covenant that limits our ability, subject to specified exceptions, to incur additional indebtedness without the prior written consent of SVB.

Loan and Security Agreement with Oxford Finance LLC

In October 2018, we entered into a Loan and Security Agreement with Oxford. The Loan and Security Agreement provided for up to $65.0 million in term loans, of we borrowed $30.0 million in October 2018. In October 2019, we repaid in full the $30.0 million that was outstanding under the Loan and Security Agreement, together with all accrued and unpaid interest and fees.

Cash Flows

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

	Year Ended December 31,		
(In thousands)	**2020**	**2019**	**2018**
Net cash used in operating activities	$ (38,633)	$ (96,445)	$ (100,811)
Net cash provided by investing activities	6,387	105,679	9,367
Net cash provided by (used in) financing activities	18,372	(30,316)	128,261
Net increase (decrease) in cash, cash equivalents and restricted cash	$ (13,874)	$ (21,082)	$ 36,817

Operating Activities

During the year ended December 31, 2020, operating activities used $38.6 million of cash primarily resulting from our net loss of $51.0 million and changes in our operating assets and liabilities of $2.4 million, partially offset by non-cash adjustments of $14.7 million. Net cash used by changes in our operating assets and liabilities during the year ended December 31, 2020 consisted of a $8.9 million decrease in accounts payable and accrued expenses, partially offset by a $4.9 million decrease in accounts receivable and a $1.7 million decrease in prepaid expenses and other assets. The net decrease in accounts payable and accrued expenses was primarily driven by lower overall operating expenses as well as expenses incurred, but not yet paid, as of December 31, 2020 compared to the year ended December 31, 2019. The decrease in accounts receivable was primarily the result of cash received from Allergan related to sales of RHOFADE made during the year ended December 31, 2019. The decrease in prepaid expenses and other assets was primarily due to amortization of the premiums for our corporate insurance policies, which we expense equally over the policy term, partially offset by prepayment of policies for 2021. Non-cash expenses of $14.7 million were primarily composed of stock-based compensation expense of $11.2 million, a charge of $2.4 million related to the change in the fair value of contingent consideration and depreciation and amortization expense of $1.3 million.

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 and changes in our operating assets and liabilities of $2.7 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 $3.2 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 increase in accounts receivable was primarily the result of the timing of cash receipts from our contract research customers. 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 legacy JAK inhibitors, 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. 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 $22.5 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 our legacy JAK inhibitors. 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 $22.5 million were primarily composed of stock-based compensation expense.

Investing Activities

During the year ended December 31, 2020, investing activities provided $6.4 million of cash consisting of proceeds from sales and maturities of marketable securities of $54.6 million, offset by purchases of marketable securities of $47.7 million and purchases of equipment and leasehold improvements of $0.5 million.

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, 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, 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.

Financing Activities

During the year ended December 31, 2020, financing activities provided $18.4 million of cash consisting of $10.9 million of net borrowings pursuant to the Loan and Security Agreement with SVB and $7.7 million of proceeds from the issuance of common stock in connection with the Purchase Agreement with Lincoln Park, partially offset by $0.1 million of finance lease payments and $0.2 million of deferred issuance costs.

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, 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 consisting of net proceeds of $100.2 million received from our public offering of common stock in October 2018, $29.9 million of net borrowings pursuant to the Loan and Security Agreement with Oxford and $0.6 million of cash received from the exercise of employee stock options, 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.

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 moderate to severe rheumatoid arthritis and potentially other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, continue the development of our preclinical compounds, and continue to discover 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 incur and will continue to incur significant legal, accounting and other expenses. 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.

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 will require additional capital to complete the clinical development of ATI-450 and ATI-1777, 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. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise sufficient additional capital or generate revenue from transactions with potential 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, our stockholders' 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;
- the impact on the timing of our preclinical studies, the recruitment, enrollment, conduct and timing of our clinical trials and our business due to the COVID-19 pandemic;
- 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. In December 2020, we entered into a sub-sublease agreement under which we sub-subleased 8,115 square feet. The sub-sublease term runs concurrent with the original sublease agreement. We occupy office and laboratory space in St. Louis, Missouri under a sublease agreement which has a term through June 2029.

In March 2020, we borrowed $11.0 million under the Loan and Security Agreement with SVB. Amounts borrowed under the Loan and Security Agreement are subject to interest only through March 2022, after which we will be required to make principal and interest payments through the maturity date of March 2024.

We enter into contracts in the normal course of business with CROs and contract manufacturing organizations for clinical trials, preclinical 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.

Segment Information

We have 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, our wholly-owned subsidiary.

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. 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. 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. 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. 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. 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.

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.

The Loan and Security Agreement with SVB provides for an annual interest rate equal to the greater of (i) the prime rate then in effect as reported in The Wall Street Journal plus 2% and (ii) 6.75%. To the extent that any present or future credit facilities that we enter into are based on a floating interest rate, we will be subject to risks relating to changes in market interest rates. In periods of rising interest rates when we have such debt outstanding, our interest expense would increase. Based upon our debt outstanding of $11.0 million as of December 31, 2020, a 100 basis-point increase in the interest rate on our loan with SVB would result in $0.1 million of additional interest expense on an annualized basis.

The uncertainty that exists with respect to the economic impact of the global COVID-19 pandemic has introduced significant volatility in the financial markets during and subsequent to the year ended December 31, 2020.

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

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the consolidated financial statements that was communicated or required to be communicated to the audit committee and that (i) relates to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which it relates.

Fair Value of Contingent Consideration Liability

As described in Notes 2 and 4 to the consolidated financial statements, the Company initially recorded a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon the achievement of certain development, regulatory and commercial milestones, as well as future projected sales performance, at its estimated fair value on the date of acquisition. Management evaluates fair value estimates of contingent consideration liabilities on a quarterly basis. Management estimates the fair value of the contingent consideration liability associated with sales milestones and royalties by estimating future sales levels, assigning an achievement probability and

discounting the associated cash payment to its present value using a risk-adjusted rate of return. Management estimates the fair value of the contingent consideration liability for regulatory milestones by assigning an achievement probability to each potential milestone and discounting the associated cash payments to their present values using a credit-risk-adjusted interest rate. Changes in the fair value of the contingent consideration are recorded as income or expense in the Company's consolidated statement of operations and comprehensive loss. Significant assumptions used in management's estimates include the probability of success of both achieving regulatory milestones and commencing commercialization, which are based upon an asset's current stage of development. As of and for the year ended December 31, 2020, management recorded a contingent consideration liability of $4.1 million and expense of $2.4 million.

The principal considerations for our determination that performing procedures relating to the fair value of the contingent consideration liability is a critical audit matter are the significant judgment by management when developing the fair value estimate, which in turn led to a high degree of auditor judgment, subjectivity and effort in evaluating the significant assumptions related to the probability of success of both achieving regulatory milestones and commencing commercialization. Also, the audit effort involved the use of professionals with specialized skill and knowledge.

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included, among others, testing management's process for developing the fair value of the contingent consideration liability and evaluating the reasonableness of the valuation model and assumptions related to the probability of success of both achieving regulatory milestones and commencing commercialization. Evaluating management's assumptions related to the probability of success of both achieving regulatory milestones and commencing commercialization involved assessing whether the assumptions used by management were reasonable considering the agreements associated with the transaction and the consistency with industry studies and the stage of product development. Professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of management's valuation model.

/s/ PricewaterhouseCoopers LLP
Philadelphia, Pennsylvania
February 25, 2021

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, 2020	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	$ 22,063	$ 34,187
Restricted cash	—	1,750
Marketable securities	32,068	39,078
Accounts receivable, net	772	704
Prepaid expenses and other current assets	2,590	3,118
Discontinued operations - current assets	—	4,966
Total current assets	57,493	83,803
Property and equipment, net	1,654	2,470
Intangible assets	7,123	7,199
Other assets	4,514	4,825
Total assets	$ 70,784	$ 98,297
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,254	$ 9,917
Accrued expenses	5,906	7,721
Current portion of lease liabilities	603	637
Discontinued operations - current liabilities	3,111	4,157
Total current liabilities	14,874	22,432
Other liabilities	3,179	3,736
Long-term debt, net	10,653	—
Contingent consideration	4,061	1,668
Deferred tax liability	367	549
Total liabilities	33,134	28,385
Commitments and contingencies (Note 20)		
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at December 31, 2020 and December 31, 2019	—	—
Common stock, $0.00001 par value; 100,000,000 shares authorized at December 31, 2020 and December 31, 2019; 45,109,314 and 41,485,638 shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	542,286	523,505
Accumulated other comprehensive loss	(94)	(66)
Accumulated deficit	(504,542)	(453,527)
Total stockholders' equity	37,650	69,912
Total liabilities and stockholders' equity	$ 70,784	$ 98,297

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,		
	2020	2019	2018
Revenues:			
Contract research	$ 5,786	$ 4,227	$ 4,651
Other revenue	696	—	1,500
Total revenue	6,482	4,227	6,151
Costs and expenses:			
Cost of revenue	5,133	4,055	4,329
Research and development	31,731	64,899	60,841
General and administrative	20,530	27,827	25,761
Goodwill impairment	—	18,504	—
Total costs and expenses	57,394	115,285	90,931
Loss from operations	(50,912)	(111,058)	(84,780)
Other income (expense), net	(424)	(2,484)	2,676
Loss from continuing operations before income taxes	(51,336)	(113,542)	(82,104)
Income tax benefit	(182)	—	—
Loss from continuing operations	(51,154)	(113,542)	(82,104)
Income (loss) from discontinued operations, net of tax	139	(47,812)	(50,634)
Net loss	$ (51,015)	$ (161,354)	$ (132,738)
Net loss per share, basic and diluted	$ (1.20)	$ (3.90)	$ (4.03)
Weighted average common shares outstanding, basic and diluted	42,539,293	41,323,921	32,909,762
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities, net of tax of $0	$ (2)	$ 28	$ 145
Foreign currency translation adjustment	(26)	(25)	32
Total other comprehensive income (loss)	(28)	3	177
Comprehensive loss	$ (51,043)	$ (161,351)	$ (132,561)

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 Loss	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
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 restricted stock units	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 restricted stock units	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
Exercise of stock options and vesting of restricted stock units	1,390,922	—	(669)	—	—	(669)
Issuance of common stock in connection with an equity purchase agreement, net of offering costs of $168	2,232,754	—	7,865	—	—	7,865
Fair value of warrants issued in connection with debt financing	—	—	378	—	—	378
Unrealized loss on marketable securities	—	—	—	(2)	—	(2)
Foreign currency translation adjustment	—	—	—	(26)	—	(26)
Stock-based compensation expense	—	—	11,207	—	—	11,207
Net loss	—	—	—	—	(51,015)	(51,015)
Balance at December 31, 2020	45,109,314	$ —	$ 542,286	$ (94)	$ (504,542)	$ 37,650

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,		
	2020	**2019**	**2018**
Cash flows from operating activities:			
Net loss	$ (51,015)	$ (161,354)	$ (132,738)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	1,324	6,409	1,879
Stock-based compensation expense	11,207	16,177	20,055
Change in fair value of contingent consideration	2,393	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	(182)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	4,898	(809)	(4,380)
Prepaid expenses and other assets	1,689	3,233	62
Accounts payable	(5,219)	(3,160)	6,964
Accrued expenses	(3,728)	(1,967)	6,792
Net cash used in operating activities	(38,633)	(96,445)	(100,811)
Cash flows from investing activities:			
Purchases of property and equipment	(453)	(1,613)	(1,356)
Acquisition of RHOFADE	—	—	(67,122)
Disposition of RHOFADE	—	34,186	—
Purchases of marketable securities	(47,714)	(137,385)	(161,598)
Proceeds from sales and maturities of marketable securities	54,554	210,491	239,443
Net cash provided by investing activities	6,387	105,679	9,367
Cash flows from financing activities:			
Proceeds from issuance of common stock in connection with public offering, net of issuance costs	—	—	100,205
Proceeds from issuance of common stock in connection with an equity purchase agreement, net of issuance costs	7,737	—	—
Proceeds from debt financing (including warrants), net of issuance costs	10,913	—	29,910
Repayment of debt	—	(30,000)	—
Payment of Confluence development milestone	—	—	(1,783)
Finance lease payments	(137)	(523)	(648)
Deferred issuance costs	(211)	—	—
Proceeds from exercise of employee stock options and the issuance of stock	70	207	577
Net cash provided by (used in) financing activities	18,372	(30,316)	128,261
Net increase (decrease) in cash, cash equivalents and restricted cash	(13,874)	(21,082)	36,817
Cash, cash equivalents and restricted cash at beginning of period	35,937	57,019	20,202
Cash, cash equivalents and restricted cash at end of period	$ 22,063	$ 35,937	$ 57,019
Supplemental disclosure of non-cash investing and financing activities:			
Additions to property and equipment included in accounts payable	$ —	$ 124	$ 161
Fair value of warrants issued in connection with debt financing	$ 378	$ —	$ —
Property and equipment obtained pursuant to finance lease financing arrangements	$ —	$ —	$ 2,131
Fair value of stock issued in connection with Confluence development milestone	$ —	$ —	$ 2,215
Offering costs included in accounts payable	$ —	$ —	$ 210
Operating lease asset recorded as a result of new accounting standard	$ —	$ 2,132	$ —
Fair value of common stock issued in connection with an equity purchase agreement	$ 263	$ —	$ —

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

ACLARIS THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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 clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases. In addition to developing its novel drug candidates, the Company is pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize its novel drug candidates.

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. As of December 31, 2020, the Company had cash, cash equivalents and marketable securities of $54.1 million and an accumulated deficit of $504.5 million. 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 will require additional capital to complete the clinical development of ATI-450 and ATI-1777, to develop its preclinical compounds, and to support its discovery efforts.

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 actively seek partners for its drug candidates and commercial products. As a result of this decision, the Company restructured its operations and reduced its workforce, which lowered operating costs. In October 2019, the Company sold the worldwide rights to RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE") to further its focus on its development programs and improve cash flow. In March 2020, the Company borrowed $11.0 million under a term loan facility with Silicon Valley Bank. In August 2020, the Company entered into an equity purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"). As of December 31, 2020, the Company had sold 2,111,170 shares of common stock to Lincoln Park under the Purchase Agreement for net proceeds of $7.7 million. The Company did not sell any additional shares prior to terminating the Purchase Agreement in January 2021 in connection with a public offering of common stock in which it sold 6,306,271 shares of its common stock for net proceeds of $103.5 million.

The Company's plans to further address its liquidity needs 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) identifying third-party partners to further develop, obtain marketing approval for and/or commercialize its drug candidates, 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.

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.

The Company's ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If the Company is unable to raise sufficient additional capital or generate revenue from transactions with potential 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 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 does not believe that substantial doubt exists about its ability to continue as a going concern. 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles 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 (for periods prior to its dissolution in 2018). All significant intercompany transactions have been eliminated. Based upon the Company's revenue, 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.

Reclassifications

Certain prior year amounts have been reclassified to conform to the current year financial statement presentation.

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).

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. The COVID-19 pandemic has resulted in a global slowdown in economic activity. As of the date of issuance of these financial statements, the Company is not aware of any specific event or circumstance that would require an update to its estimates, assumptions and judgments or revise the carrying value of its assets or liabilities. 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 and ESKATA (hydrogen peroxide) topical solution, 40% (w/w) ("ESKATA"), its non-marketed product approved by the U.S. Food and Drug Administration, 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 is presented in 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 and as such, recognizes revenue in the amount which it has the right to invoice. ASC Topic 606 also provides an optional exemption, which the Company has elected to apply, from disclosing remaining performance obligations when revenue is recognized from the satisfaction of the performance obligation in accordance with the "right to invoice" practical expedient.

The Company 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, the Company had two active grants from NIH related to early-stage research. There are no remaining funds available under the grants.

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 counterparty, 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 three months or less at acquisition date to be cash equivalents. Cash equivalents, which have consisted of money market accounts and commercial paper, are stated at fair value. Total cash, cash equivalents and restricted cash as shown in the consolidated statements of cash flows as of December 31, 2020 and 2019 includes $0 and $1.8 million, respectively, of restricted cash, consisting of funds in escrow pursuant to the asset purchase agreement with EPI Health, LLC ("EPI Health") (see Note 15).

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 either quoted prices in active markets for identical securities or 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 (expense), 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.

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 continuing 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 consist of a drug discovery platform the Company acquired through the acquisition of Confluence, and prior to the disposition in 2019, also included the intellectual property rights related to RHOFADE. 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. 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 or otherwise impaired.

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 $27.6 million, 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).

During the years ended December 31, 2020 and 2019, the Company did not record an IPR&D impairment.

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 impairment test performed by the Company is a qualitative assessment based upon the then current facts and circumstances related to operations of the reporting unit. 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 a 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 $18.5 million.

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 a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon the achievement of certain development, regulatory and commercial milestones, as well as future projected sales performance, at its estimated fair value on the date of acquisition. The ultimate amount of future payments, if any, is based on criteria such as sales performance and the achievement of certain regulatory and sales milestones. The Company estimates the fair value of the contingent consideration liability related to the achievement of regulatory milestones by assigning an achievement probability to each potential milestone and discounting the associated cash payment to its present value using a credit-risk-adjusted interest rate. The Company estimates the fair value of the contingent consideration liability associated with sales milestones and royalties by estimating future sales levels, assigning an achievement probability and discounting the associated cash payments to their present values using a risk-adjusted rate of return. Significant assumptions used in the Company's estimates include the probability of success of both achieving regulatory milestones and commencing commercialization, which are based upon an asset's current stage of development and ranged between 4% and 15%. The Company evaluates fair value estimates of contingent consideration liabilities on a quarterly basis. Any change in fair value reflects 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 candidate, 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 and comprehensive loss.

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 measures the compensation expense of stock-based awards granted to consultants using the grant date fair value of the award. The Company recognizes compensation expense over the period during which services are rendered by the consultant.

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.

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 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 warrants and the assumed vesting of RSUs, if dilutive. Since the Company was in a net loss position, basic and diluted net loss per share was the same for each of the periods presented.

Fair Value Measurements

Certain assets and liabilities are carried at fair value under GAAP. Fair value is defined as the exchange price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. Financial assets and liabilities carried at fair value are to be classified and disclosed in one of the following three levels of the fair value hierarchy, of which the first two are considered observable and the last is considered unobservable:

- Level 1 — Quoted prices in active markets for identical assets or liabilities.

- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents, marketable securities and contingent consideration are carried at fair value, determined according to the fair value hierarchy described above. The carrying value of the Company's accounts payable and accrued expenses approximate fair value due to the short-term nature of these liabilities. The carrying value of the Company's debt approximates fair value due to the debt bearing a variable interest rate which is reflective of current market rates.

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. 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. 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.

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 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 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 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. The Company adopted 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. 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. The adoption of ASU 2016-02 resulted in the Company 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 the Company's consolidated statement of operations and comprehensive loss 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 $35.2 million. In addition, EPI Health agreed to pay the Company (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 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 certain agreements with third parties.

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 Sales, LLC ("Allergan") pursuant to an asset purchase agreement. The acquisition of RHOFADE was accounted for as an asset acquisition in accordance with FASB ASC 805-50.

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

(In thousands)		
Inventory	$	893
Intangible assets, net		66,229
Total assets acquired	$	67,122

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 and non-recurring basis, and indicate the level of the fair value hierarchy utilized to determine such fair values:

	December 31, 2020			
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 14,955	$ 1,500	$ —	$ 16,455
Marketable securities	—	32,068	—	32,068
Total assets	$ 14,955	$ 33,568	$ —	$ 48,523
Liabilities:				
Acquisition-related contingent consideration	$ —	$ —	$ 4,061	$ 4,061
Total liabilities	$ —	$ —	$ 4,061	$ 4,061

	December 31, 2019			
(In thousands)	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

As of December 31, 2020 and 2019, the Company's cash equivalents included a money market fund, which was valued based upon Level 1 inputs. Cash equivalents as of December 31, 2020 also included commercial paper, which was valued based upon Level 2 inputs. The Company's marketable securities as of December 31, 2020 and 2019 included U.S. government agency debt securities, commercial paper and asset-backed debt securities, which were valued based upon Level 2 inputs. Marketable securities as of December 31, 2019 also included corporate debt securities, which were valued based upon Level 2 inputs.

In determining the fair value of its Level 2 investments, the Company relied on quoted prices for identical securities in markets that are not active. These quoted prices were obtained by the Company with the assistance of a third-party pricing service based on available trade, bid and other observable market data for identical securities. Quarterly, the Company compares the quoted prices obtained from the third-party pricing service to other available independent pricing information to validate the reasonableness of the quoted prices provided. The Company evaluates whether adjustments to third-party pricing are 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, 2020 and 2019, there were no transfers between Level 1, Level 2 and Level 3.

The increase in contingent consideration of $2.4 million during the year ended December 31, 2020 was primarily due to updates to the Company's assumptions resulting from the successful completion of a Phase 1 clinical trial for ATI-450 and the submission and allowance of an Investigational New Drug Application ("IND") for ATI-1777. The change in acquisition-related contingent consideration of $0.7 million during the year ended December 31, 2019 was the result of updates to the Company's assumptions as a result of the submission and allowance of an IND for ATI-450.

As of December 31, 2020 and 2019, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

	December 31, 2020			
(In thousands)	Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Commercial paper	$ 20,483	$ —	$ —	$ 20,483
Asset-backed debt securities	4,036	1	—	4,037
U.S. government agency debt securities	7,547	1	—	7,548
Total marketable securities	$ 32,066	$ 2	$ —	$ 32,068

	December 31, 2019			
(In thousands)	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 debt 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

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	December 31, 2020	December 31, 2019
Computer equipment	$ 1,197	$ 1,315
Finance lease right-of-use assets	—	435
Lab equipment	1,340	1,250
Furniture and fixtures	617	647
Leasehold improvements	1,123	889
Property and equipment, gross	4,277	4,536
Accumulated depreciation	(2,623)	(2,066)
Property and equipment, net	$ 1,654	$ 2,470

Depreciation expense was $1.1 million, $1.5 million and $1.2 million for the years ended December 31, 2020, 2019 and 2018, respectively.

6. Intangible Assets

Intangible assets consisted of the following:

		Gross Cost		Accumulated Amortization	
(In thousands, except years)	Remaining Life (years)	December 31, 2020	December 31, 2019	December 31, 2020	December 31, 2019
Other intangible assets	6.6	751	751	257	181
IPR&D	na	6,629	6,629	—	—
Total intangible assets		$ 7,380	$ 7,380	$ 257	$ 181

Amortization expense was $75 thousand for each of the years ended December 31, 2020, 2019 and 2018.

As of December 31, 2020, estimated future amortization expense is as follows:

(In thousands)	Year Ending December 31,
2021	$ 75
2022	75
2023	75
2024	75
2025	75
Thereafter	119
Total	$ 494

7. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	December 31, 2020	December 31, 2019
Employee compensation expenses	$ 3,971	$ 3,321
Research and development expenses	761	2,857
Other	1,174	1,543
Total accrued expenses	$ 5,906	$ 7,721

8. Debt

Loan and Security Agreement – Silicon Valley Bank

In March 2020, the Company entered into a Loan and Security Agreement with Silicon Valley Bank ("SVB"). The Loan and Security Agreement provides for $11.0 million in term loans, of which the Company borrowed the entire amount on March 30, 2020. The Loan and Security Agreement is secured by substantially all of the assets of the Company other than intellectual property. In connection with the Loan and Security Agreement, the Company issued to SVB a warrant to purchase up to 460,251 shares of common stock (the "Warrant") (see Note 9). The proceeds of the Loan and Security Agreement were allocated to the term loan and Warrant using a relative fair value approach.

The term loan repayment schedule provides for interest only payments beginning April 1, 2020 and continuing through March 1, 2022, followed by 24 consecutive equal monthly installments of principal, plus monthly payments of accrued interest, starting on April 1, 2022 and continuing through the maturity date of March 1, 2024. All outstanding principal and accrued and unpaid interest will be due and payable on the maturity date. The Loan and Security Agreement provides for an annual interest rate equal to the greater of (i) the prime rate then in effect as reported in The Wall Street Journal plus 2% and (ii) 6.75%.

The Loan and Security Agreement includes a final payment fee equal to 5% of the original principal amount borrowed. The Company has the option to prepay the outstanding balance of the term loans in full, subject to a prepayment premium of (i) 3% of the original principal amount borrowed for any prepayment on or prior to the first anniversary of March 30, 2020, (ii) 2% of the original principal amount borrowed for any prepayment after the first anniversary and on or before the second anniversary of March 30, 2020 or (iii) 1% of the original principal amount borrowed for any prepayment after the second anniversary of March 30, 2020 but before March 1, 2024.

Loan and Security Agreement – Oxford Finance LLC

In October 2018, the Company entered into a Loan and Security Agreement with Oxford Finance LLC. The Loan and Security Agreement provided for up to $65.0 million in term loans, of which the Company borrowed $30.0 million in October 2018. In October 2019, the Company repaid in full the $30.0 million that was outstanding under the Loan and Security Agreement, together with all accrued and unpaid interest and fees.

9. Stockholders' Equity

Preferred Stock

As of December 31, 2020 and 2019, 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, 2020 and 2019.

Common Stock

As of December 31, 2020 and 2019, 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, 2020.

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 $106.9 million. The Company paid underwriting discounts and commissions of $6.4 million to the underwriters in connection with the offering. In addition, the Company incurred expenses of $0.3 million in connection with the offering. The net offering proceeds received by the Company, after deducting underwriting discounts and commissions and offering expenses, were $100.2 million.

Warrants

The Warrant issued to SVB in March 2020 had an initial exercise price of $0.956 per share, subject to adjustment as provided in the Warrant. The Warrant became immediately exercisable in full upon the funding of the term loan facility. The Company assigned a fair value of $0.4 million to the Warrant using a Black-Scholes valuation methodology, and also concluded that the Warrant was indexed to its own stock and therefore classified the Warrant as an equity instrument. In January 2021, SVB net exercised the Warrant in full, and the Company issued to SVB 388,119 shares of common stock.

Equity Purchase Agreement with Lincoln Park Capital Fund, LLC

In August 2020, the Company entered into the Purchase Agreement with Lincoln Park which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company may sell to Lincoln Park, at its discretion, up to $15.0 million of shares of its common stock over the 36-month term of the Purchase Agreement. Upon execution of the Purchase Agreement, the Company issued 121,584 shares of its common stock to Lincoln Park as commitment shares in accordance with the closing conditions contained within the Purchase Agreement. The commitment shares were valued using the closing price of the Company's common stock on the effective date of the Purchase Agreement resulting in an aggregate fair value of $0.3 million. Through December 31, 2020, the Company sold 2,111,170 shares of its common stock to Lincoln Park under the Purchase Agreement for net proceeds of $7.7 million. The Company terminated the Purchase Agreement in January 2021. The Company did not sell any additional shares prior to terminating the Purchase Agreement in January 2021 in connection with the public offering of common stock described below (see Note 21).

10. Stock-Based Awards

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 initial public offering. 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, 2020, 2,423,020 shares remained available for grant under the 2015 Plan. As of January 1, 2021, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 1,804,372 shares.

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-stockholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The Company had 443,000 stock options and 28,895 RSUs outstanding as of December 31, 2020 under the 2017 Inducement Plan. 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.

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 549,561 and 745,735 were outstanding as of December 31, 2020 and 2019, respectively. Stock options granted under the 2012 Plan vested over four years and expire after ten years.

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, 2020, 2019 and 2018 were as follows:

	Year Ended December 31,		
	2020	2019	2018
Risk-free interest rate	0.87 %	2.27 %	2.66 %
Expected term (in years)	6.1	6.2	6.3
Expected volatility	85.19 %	99.36 %	96.78 %
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, 2020, 2019 and 2018:

(In thousands, except share and per share data and years)	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	3,328,757	$ 20.69	8.3	$ 19,812
Granted	1,459,800	20.97		
Exercised	(59,450)	9.70		724
Forfeited and cancelled	(447,026)	24.62		
Outstanding as of December 31, 2018	4,282,081	$ 20.53	7.9	$ 2,404
Granted	44,500	5.75		
Exercised	(142,779)	1.33		112
Forfeited and cancelled	(1,081,581)	23.01		
Outstanding as of December 31, 2019	3,102,221	$ 20.33	6.6	$ 148
Granted	734,800	1.30		
Exercised	(53,737)	1.30		145
Forfeited and cancelled	(911,786)	22.41		
Outstanding as of December 31, 2020	2,871,498	$ 15.16	6.8	$ 4,890
Options vested and expected to vest as of December 31, 2020	2,871,498	$ 15.16	6.8	$ 4,890
Options exercisable as of December 31, 2020	1,844,197	$ 18.92	5.8	$ 1,424

The weighted average grant date fair value of stock options granted during the years ended December 31, 2020, 2019 and 2018 was $0.93, $4.63 and $16.55 per share, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2020, 2019 and 2018.

(In thousands, except share and per share data)	Number of Shares	Weighted Average Grant Date Fair Value Per Share	Aggregate Intrinsic Value
Outstanding as of December 31, 2017	283,553	$ 27.02	
Granted	552,060	19.03	
Vested	(140,497)	27.22	$ 2,158
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	$ 799
Forfeited and cancelled	(510,990)	10.63	
Outstanding as of December 31, 2019	3,592,915	$ 4.62	
Granted	1,168,805	1.36	
Vested	(1,804,429)	3.33	$ 2,607
Forfeited and cancelled	(713,134)	4.77	
Outstanding as of December 31, 2020	2,244,157	$ 3.83	

Stock-Based Compensation

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

(In thousands)	Year Ended December 31, 2020	2019	2018
Cost of revenue	$ 946	$ 703	$ 766
Research and development	2,919	5,091	6,480
General and administrative	7,342	10,288	9,317
Total stock-based compensation expense	$ 11,207	$ 16,082	$ 16,563

As of December 31, 2020, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $4.2 million and $5.5 million, respectively, which is expected to be recognized over weighted average periods of 1.3 years and 1.8 years, respectively.

11. Net Loss per Share

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

(In thousands, except for share and per share data)	Year Ended December 31, 2020	2019	2018
Numerator:			
Net loss	$ (51,015)	$ (161,354)	$ (132,738)
Denominator:			
Weighted average shares of common stock outstanding, basic and diluted	42,539,293	41,323,921	32,909,762
Net loss per share, basic and diluted	$ (1.20)	$ (3.90)	$ (4.03)

The Company's potentially dilutive securities, which included stock options, RSUs and warrants, 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 shares of common stock 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, 2020, 2019 and 2018. All share amounts presented in the table below represent the total number outstanding as of December 31 of each year.

	December 31, 2020	2019	2018
Options to purchase common stock	2,871,498	3,102,221	4,282,081
Restricted stock unit awards	2,244,157	3,592,915	626,407
Warrants	460,251	—	—
Total potential shares of common stock	5,575,906	6,695,136	4,908,488

12. Leases

The Company has operating leases for office space and laboratory facilities, and had finance leases for its laboratory equipment. 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 $0.2 million during the year ended December 31, 2019. The components of lease expense were as follows:

(In thousands)	Year Ended December 31, 2020	2019
Operating lease expense	$ 1,013	$ 808
Finance Leases:		
Amortization of right-to-use assets	$ 113	$ 443
Interest expense	5	87
Total finance lease expenses	$ 118	$ 530

Rent expense was $1.0 million, $1.0 million and $0.9 million for the years ended December 31, 2020, 2019 and 2018, respectively, which was recognized on a straight-line basis over the term of the lease.

Operating Leases

Agreements for Office Space

The Company has 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 December 2020, the Company entered into a sub-sublease agreement under which it sub-subleased 8,115 square feet. The sub-sublease term runs concurrent with the original sublease agreement.

In February 2019, the Company entered into a sublease agreement with a third party for 20,433 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:

(In thousands)	December 31, 2020	December 31, 2019
Operating Leases:		
Gross cost	$ 5,240	$ 5,213
Accumulated amortization	(1,111)	(480)
Other assets	$ 4,129	$ 4,733
Current portion of lease liabilities	$ 603	$ 526
Other liabilities	2,894	3,548
Total operating lease liabilities	$ 3,497	$ 4,074

Finance Leases

Laboratory Equipment

The Company leased laboratory equipment which it 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, and which terms ended 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:

(In thousands) **Finance Leases:**	December 31, 2020	December 31, 2019
Property and equipment, gross	$ —	$ 435
Accumulated depreciation	—	(322)
Property and equipment, net	$ —	$ 113
Current portion of lease liabilities	$ —	$ 111
Other liabilities	—	21
Total finance lease liabilities	$ —	$ 132

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

(In thousands, except for years and percentages)	Year Ended December 31,	
Supplemental Cash Flow Lease Information:	**2020**	**2019**
Operating cash flows from operating leases	$ 907	$ 755
Operating cash flows from finance leases	$ 5	$ 87
Financing cash flows from finance leases	$ 137	$ 523
Leased assets obtained in exchange for new operating lease liabilities	$ —	$ 3,060
Weighted-Average Remaining Lease Term (in years):		
Operating leases	6.0	6.8
Finance leases	—	0.9
Weighted-Average Discount Rate:		
Operating leases	10.1 %	10.1%
Finance leases	10.0 %	10.0%

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

(In thousands) **Year Ending December 31,**	Operating Leases
2021	$ 924
2022	949
2023	866
2024	343
2025	352
Thereafter	1,301
Total undiscounted lease payments	4,735
Less: unrecognized interest	(1,238)
Total lease liability	$ 3,497

13. Income Taxes

During the years ended December 31, 2020, 2019 and 2018, 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:

(In thousands)	Year Ended December 31, 2020	2019	2018
U.S. operations	$ (51,215)	$ (161,192)	$ (132,473)
Foreign operations	18	(162)	(265)
Loss before income taxes	$ (51,197)	$ (161,354)	$ (132,738)

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, 2020	2019	2018
Federal statutory income tax rate	(21.0)%	(21.0)%	(21.0)%
State taxes, net of federal benefit	(7.5)	(6.6)	(3.5)
Research and development tax credits	(2.6)	(1.5)	(2.1)
Permanent differences	2.6	3.0	0.8
Change in deferred tax asset valuation allowance	28.1	26.2	25.7
Effective income tax rate	(0.4)%	0.1 %	(0.1)%

Deferred tax liabilities, net consisted of the following:

(In thousands)	December 31, 2020	2019
Deferred tax assets:		
Net operating loss carryforwards	$ 101,277	$ 90,298
Capitalized start-up costs	6,509	6,904
Research and development tax credit carryforwards	8,732	7,417
Capitalized research and development expense	4,611	4,456
Stock-based compensation expense	14,526	12,973
Accrued compensation	745	588
Lease liabilities	888	945
Other	602	618
Total deferred tax assets	137,890	124,199
Deferred tax liabilities:		
Property and equipment	(209)	(206)
Intangible asset	(2,033)	(1,741)
Right-to-use assets	(1,026)	(1,235)
Other	(430)	(600)
Total deferred tax liabilities	(3,698)	(3,782)
Valuation allowance	(134,559)	(120,966)
Deferred tax liabilities, net	$ (367)	$ (549)

As of December 31, 2020, the Company had federal and state net operating loss ("NOL") carryforwards of $367.6 million and $369.6 million, respectively, which will begin to expire in 2032. As of December 31, 2020, the Company also had federal research and development tax credit carryforwards of $8.6 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. The Company also has $0.2 million 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 July 20, 2020. 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 after July 20, 2020. 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, 2020 and 2019. 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, 2020, 2019 and 2018 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,		
(In thousands)	**2020**	**2019**	**2018**
Valuation allowance at beginning of year	$ (120,966)	$ (80,985)	$ (46,878)
Decreases recorded as benefit to income tax provision	—	—	—
Decreases recorded to opening balance sheet	58	—	—
Increases recorded to income tax provision	(13,651)	(39,981)	(34,107)
Valuation allowance as of end of year	$ (134,559)	$ (120,966)	$ (80,985)

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 2017 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

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, in November 2018 the Company entered into a master services agreement with a subsidiary of Mallinckrodt plc pursuant to which Confluence provides laboratory services to the subsidiary ("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, 2020 and 2019, the Company invoiced Mallinckrodt for $0.3 million and $0.1 million, respectively, under the master services agreement. As of December 31, 2020 and 2019, the Company had $0 of outstanding accounts receivable balances from Mallinckrodt. Mr. Reasons had no financial interest in these transactions.

15. Agreements Related to Intellectual Property

Asset Purchase Agreement – EPI Health, LLC

In October 2019, the Company sold RHOFADE to EPI Health pursuant to an asset purchase agreement. EPI Health agreed to pay the Company a high single-digit royalty calculated as a percentage of net sales on a country-by-country basis until the date that the patent rights related to RHOFADE have expired or, if later, ten years from the date of the first commercial sale of RHOFADE in such country. The Company recorded royalty income under the asset purchase agreement of $0.7 million and $0 during the years ended December 31, 2020 and 2019, respectively. Royalty income is included in other revenue on the consolidated statements of operations and comprehensive loss. EPI Health has also agreed to pay the Company 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 asset purchase agreement, 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 the disposition in any territory outside of the United States, subject to specified exceptions.

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. The Company incurred royalties earned by Allergan under the asset purchase agreement of $0, $1.4 million and $0.1 million during the years ended December 31, 2020, 2019 and 2018, respectively.

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, a development milestone specified in the Confluence Agreement was achieved, as a result of which the Company paid the former Confluence equity holders $2.5 million in cash and issued 253,208 shares of its common stock with a fair value of $2.2 million. Under the Confluence Agreement, the Company 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, 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 to the payments described above, 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 consideration 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. During the year ended December 31, 2019, the Company made a milestone payment of $4.0 million 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. In connection with an amendment of the agreement with Rigel in October 2019, the Company paid Rigel an amendment fee of $1.5 million during the year ended December 31, 2020.

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 $0.4 million, $0.7 million and $0.7 million for the years ended December 31, 2020, 2019 and 2018, 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 were entitled to receive one-time cash severance payments which were not contingent upon providing additional services to the Company. In addition, certain noticed employees earned retention bonuses if they continued 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 expensed the cost of retention bonuses for noticed employees over their respective service terms. During the year ended December 31, 2020, the Company recognized aggregate expenses of $0.1 million and made payments of $0.3 million related to termination benefits for employees. During the year ended December 31, 2019, the Company recognized aggregate expenses of $2.7 million and made payments of $2.3 million related to termination benefits for employees.

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,		
(In thousands, except share and per share data)	**2020**	**2019**	**2018**
Revenues:			
Product sales, net	$ 424	$ 13,896	$ 3,940
Total revenue, net	424	13,896	3,940
Costs and expenses:			
Cost of revenue (excludes amortization)	—	4,522	1,969
Research and development	1	503	2,168
Sales and marketing	283	23,112	47,827
General and administrative	1	2,929	2,058
Intangible asset impairment	—	27,638	—
Amortization of definite-lived intangible	—	4,426	552
Total costs and expenses	285	63,130	54,574
Income (loss) from operations	139	(49,234)	(50,634)
Other income, net	—	1,422	—
Income (loss) from discontinued operations before income taxes	139	(47,812)	(50,634)
Income tax benefit	—	—	—
Net income (loss) from discontinued operations	$ 139	$ (47,812)	$ (50,634)
Net income (loss) from discontinued operations per share, basic and diluted	$ 0.00	$ (1.16)	$ (1.54)
Weighted average common shares outstanding, basic and diluted	42,539,293	41,323,921	32,909,762

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

	Year Ended December 31,		
(In thousands)	**2020**	**2019**	**2018**
ESKATA	$ —	$ 312	$ 2,804
RHOFADE	424	13,584	1,136
Total product sales, net	$ 424	$ 13,896	$ 3,940

The Company recorded $0.4 million of RHOFADE product sales, net during the year ended December 31, 2020 due to a reversal of previously accrued product sales-related reserves.

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

(In thousands)	December 31, 2020	December 31, 2019
Accounts receivable, net	$ —	$ 4,966
Discontinued operations - current assets	$ —	$ 4,966
Accounts payable	$ 1,175	$ 1,705
Accrued expenses	1,936	2,452
Discontinued operations - current liabilities	$ 3,111	$ 4,157

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 included $5.0 million related to amounts invoiced by Allergan for sales of RHOFADE.

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,	
(In thousands)	2020	2019
Depreciation and amortization	$ —	$ 313
Stock-based compensation expense	—	95
Intangible asset impairment charge	—	27,638
Loss on disposal of property and equipment	—	248
	—	28,294
Gain on sale of RHOFADE	—	1,670
Total non-cash items	$ —	$ 26,624

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 $0.2 million 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 $27.6 million 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, 2020, 2019 and 2018 are summarized in the tables below:

(In thousands) Year Ended December 31, 2020	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 696	$ 13,319	$ (7,533)	$ 6,482
Cost of revenue	—	12,228	(7,095)	5,133
Research and development	32,170	—	(439)	31,731
General and administrative	—	2,794	17,736	20,530
Loss from operations	$ (31,474)	$ (1,703)	$ (17,735)	$ (50,912)
Income (loss) from discontinued operations	$ 140	$ —	$ (1)	$ 139

Year Ended December 31, 2019	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ —	$ 16,824	$ (12,597)	$ 4,227
Cost of revenue	—	16,253	(12,198)	4,055
Research and development	65,298	—	(399)	64,899
General and administrative	620	2,738	24,469	27,827
Goodwill impairment	18,504	—	—	18,504
Loss from operations	$ (84,422)	$ (2,167)	$ (24,469)	$ (111,058)
Loss from discontinued operations	$ (46,305)	$ —	$ (1,507)	$ (47,812)

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
General and administrative	160	2,181	23,420	25,761
Loss from operations	$ (60,915)	$ (445)	$ (23,420)	$ (84,780)
Loss from discontinued operations	$ (48,576)	$ —	$ (2,058)	$ (50,634)

Intersegment Revenue

Revenue for the contract research segment included $7.5 million, $12.6 million and $8.5 million for services performed on behalf of the therapeutics segment for the years ended December 31, 2020, 2019 and 2018, 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 filed a motion to dismiss the consolidated

amended complaint on April 17, 2020. Fulcher filed an opposition to the defendants' motion on June 15, 2020, and the defendants filed a reply to such opposition on August 4, 2020. Oral argument on the pending motion to dismiss is scheduled for February 25, 2021. The motion remains under judicial consideration.

The Company and the other defendants dispute plaintiffs' claims in the Consolidated Securities Action and intend to defend the matter vigorously. At this time, the Company cannot reasonably predict the outcome or potential loss, if any, that could result from this matter.

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. At this time, the Company cannot reasonably predict the outcome or potential loss, if any, that could result from this matter.

Product Liability Lawsuit

On December 18, 2020, plaintiff Daurie Mancini filed an amended complaint under the caption *Daurie Mancini v. Aclaris Therapeutics, Inc. et al* in the Superior Court of New Jersey Ocean County against the Company and certain third parties alleging injuries as a result of the plaintiff's alleged treatment with ESKATA in 2019. The amended complaint seeks unspecified compensatory and punitive damages. On January 19, 2021, the Company's deadline to answer, move against or otherwise respond to the amended complaint was extended until March 15, 2021.

The Company disputes plaintiff's claims and intends to defend the matter vigorously. At this time, the Company cannot reasonably predict the outcome or potential loss, if any, that could result from this matter.

21. Subsequent Events

January 2021 Public Offering

In January 2021, the Company closed a public offering in which it sold 6,306,271 shares of common stock at a price to the public of $17.50 per share, for aggregate gross proceeds of $110.4 million. The Company paid underwriting discounts and commissions of $6.6 million, and also incurred expenses of $0.3 million in connection with the offering. As a result, the net offering proceeds received by the Company, after deducting underwriting discounts, commissions and offering expenses, were $103.5 million.

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, 2020, 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, 2020, 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, 2020 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, 2020, 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 are a smaller reporting company and a non-accelerated filer under the SEC rules, 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 2021 Annual Meeting of Stockholders, or the 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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 2021 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#	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).
2.2^&	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 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on June 24, 2020).
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+	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).
10.2+	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).
10.3+	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).
10.4+	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).
10.5+	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).

10.6+	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).
10.7+	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).
10.8+	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).
10.9+	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).
10.10+	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).
10.11+	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).
10.12+*	Fourth Amended and Restated Non-Employee Director Compensation Policy.
10.13+	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).
10.14+	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).
10.15+	Employment Agreement with Frank Ruffo, dated as of September 17, 2015 (incorporated by reference to Exhibit 10.20 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 25, 2020).
10.16+*	Change in Control Severance Benefit Plan, effective January 1, 2017, as amended by First Amendment to Change in Control Severance Benefit Plan, effective October 2, 2019.
10.17	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).
10.18	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).
10.19	Second Amendment to Sublease, dated as of April 29, 2020, by and between the Registrant and Auxilium Pharmaceuticals, LLC (incorporated by reference to Exhibit 10.5 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 7, 2020).
10.20	Loan and Security Agreement, by and among the Registrant, Confluence Discovery Technologies, Inc. and Silicon Valley Bank, dated as of March 30, 2020 (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 March 31, 2020).
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 (the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document)
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document

101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

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* 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.

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, 2021

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, 2021
/s/ Frank Ruffo Frank Ruffo	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 25, 2021
/s/ Christopher Molineaux Christopher Molineaux	Chairman of the Board of Directors	February 25, 2021
/s/ Anand Mehra, M.D. Anand Mehra, M.D.	Director	February 25, 2021
/s/ William Humphries William Humphries	Director	February 25, 2021
/s/ Andrew Powell Andrew Powell	Director	February 25, 2021
/s/ Andrew Schiff Andrew Schiff	Director	February 25, 2021
/s/ Bryan Reasons Bryan Reasons	Director	February 25, 2021
/s/ Maxine Gowen Maxine Gowen	Director	February 25, 2021
/s/ Vincent Milano Vincent Milano	Director	February 25, 2021

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.

Choice of Forum

The Company's 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 the Company's behalf, (ii) any action asserting a claim for breach of a fiduciary duty owed by any of the Company's directors, officers or other employees to the Company or its stockholders, (iii) any action asserting a claim arising pursuant to any provision of the DGCL, the Company's certificate of incorporation or 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 of 1933, as amended, or the Securities Act, or the Securities Exchange Act of 1934, as amended.

In addition, the Company's bylaws provide that unless the Company consents in writing to the selection of an alternative forum, the federal district courts of the United States of America shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, and that any person or entity purchasing or otherwise acquiring or holding any interest in shares of capital stock of the Company shall be deemed to have notice of and consented to the federal forum selection provision.

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.

FOURTH 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***") (each such member, an "***Eligible Director***") will receive the compensation described in this Fourth Amended & Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service effective as of January 1, 2021 (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): $30,000

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 44,600 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 22,300 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.

CHANGE IN CONTROL SEVERANCE BENEFIT PLAN

Section 1. INTRODUCTION.

The Aclaris Therapeutics, Inc. Change in Control Severance Benefit Plan (the "***Plan***") is hereby established effective January 1, 2017 (the "***Effective Date***"). The purpose of the Plan is to provide for the payment of severance benefits to selected employees of Aclaris Therapeutics, Inc. (the "***Company***") that constitute a select group of management or highly compensated employees in the event that such employees become subject to involuntary employment terminations in connection with an acquisition of the Company. This Plan document also is the Summary Plan Description for the Plan.

For purposes of the Plan, the following terms are defined as follows:

(a) "***Affiliate***" means any "parent" or "subsidiary" of the Company as such terms are defined in Rule 405 of the Securities Act of 1933, as amended. The Plan Administrator shall have the authority to determine the time or times at which "parent" or "subsidiary" status is determined within the foregoing definition. For purposes of this Agreement, NeXeption, LLC, NeXeption, Inc., NST, LLC and NST Consulting, LLC shall not be deemed to be Affiliates of the Company.

(b) "***Annual Base Salary***" means the annualized base pay amount (excluding incentive pay, premium pay, commissions, overtime, bonuses and other forms of variable compensation) as in effect immediately prior to a Covered Termination.

(c) "***Board***" means the Board of Directors of the Company; provided, however, that if the Board has delegated authority to administer the Plan to the Compensation Committee of the Board, then "***Board***" shall also mean the Compensation Committee.

(d) "***Cause***" means cause or misconduct as defined in the Individual Severance Arrangement as in effect on the Eligible Employee's Termination Date, or in the absence of any such applicable definition, any of the following with respect to the employee: (i) the Eligible Employee'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 the Eligible Employee which constitutes gross negligence or a material breach of the Eligible Employee's duty of loyalty; (iii) any material breach by the Eligible Employee of the Company's personnel policies, including but not limited to 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 the Company; (vi) breach of fiduciary duty; or (vii) a material breach by the Eligible Employee of the Eligible Employee's Employment Agreement or any other agreement between the parties. The determination whether a termination is for Cause shall be made by the Plan Administrator in its sole and exclusive judgment and discretion.

(e) "***Change in Control***" means, in each case as approved by the Board and the requisite stockholders of the Company, (i) any consolidation or merger of the Company with or into any other corporation or other Entity or person, or any other corporate reorganization, in which the stockholders of the Company 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 the Company or any of its stockholders is a party in which in excess of 50% of the Company'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 the Company's voting power and/or outstanding capital stock, excluding any consolidation or merger effected exclusively to change the domicile of the Company; 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 the Company 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 the Company'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 in 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 the Company in connection with financings for working capital and other general corporate purposes.

(f) ***"Closing"*** means the initial closing of the Change in Control as defined in the definitive agreement executed in connection with the Change in Control. In the case of a series of transactions constituting a Change in Control, "Closing" means the first closing that satisfies the threshold of the definition for a Change in Control.

(g) "***COBRA***" means the Consolidated Omnibus Budget Reconciliation Act of 1985.

(h) "***Code***" means the Internal Revenue Code of 1986, as amended.

(i) "***Company***" means Aclaris Therapeutics, Inc. or, following a Change in Control, the surviving Entity resulting from such event.

(j) "***Covered Period***" means the period commencing sixty (60) days prior to the Closing of a Change in Control and ending twelve (12) months following the Closing of a Change in Control.

(k) "***Covered Termination***" means an employee's termination from all positions he or she then holds with the Company, which termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h) without regard to any alternative definition thereunder), and (i) which is due to a termination by the Company without Cause and other than as a result of death or disability and (ii) which occurs within the Covered Period.

(l) ***"Director"*** means a member of the Board.

(m) "***Eligible Employee***" means an employee of the Company that meets all the requirements to be eligible to receive Plan benefits as set forth in Section 2, including timely provision of an effective Release (as such term is defined in Section 2(b)).

(n) ***"Employment Agreement"*** means any individual employment offer letter, contract or agreement that an Eligible Employee has with the Company.

(o) ***"Entity"*** means a corporation, partnership, limited liability company or other entity.

(p) ***"Individual Severance Arrangement"*** means any Employment Agreement providing for severance benefits to an Eligible Employee or any other severance arrangement between the Eligible Employee and the Company other than the Plan, in each case that remains in effect through the date of a Covered Termination.

(q) "***Plan Administrator***" means the Board prior to the Closing and the Representative upon and following the Closing.

(r) "***Qualified Plan***" means a plan sponsored by the Company or an Affiliate that is intended to be qualified under Section 401(a) of the Internal Revenue Code.

(s) ***"Representative"*** means one or more members of the Board or other persons or Entities designated by the Board prior to or in connection with a Change in Control that will have authority to administer and interpret the Plan upon and following the Closing as provided in Section 8(a).

(t) "***Target Bonus***" means, with respect to an Eligible Employee, the Eligible Employee's target annual bonus under the Company's annual cash bonus plan or policy, or if the Company does not maintain such a plan or policy, the target annual bonus under the terms of the Eligible Employee's Employment Agreement or other agreement with the Company, in each case applicable to such Eligible Employee for the calendar year in which the Covered Termination of such Eligible Employee occurs. If no cash bonus plan or policy or such an agreement is in effect for the employee for the year in which the Covered Termination occurs, the Target Bonus for such employee will be $0.

(u) "***Termination Date***" means the effective date of an Eligible Employee's Covered Termination.

Section 2. ELIGIBILITY FOR BENEFITS.

(a) **Eligible Employee**. An employee of the Company is eligible to participate in the Plan if (i) the employee is a Vice President or higher level officer on any date within the Covered Period and/or the sum of the employee's Annual Base Salary and expected Target Bonus equals or exceeds $250,000; (ii) the Board has designated such employee as eligible to participate in the Plan; (iii) such employee's employment with the Company terminates due to a Covered Termination; and (iii) such employee meets the other Plan eligibility requirements set forth in this Section 2 and the Plan. The determination of whether an employee is an Eligible Employee shall be made by the Plan Administrator, in its sole discretion, and such determination shall be binding and conclusive on all persons. For the avoidance of doubt, the Company's President and Chief Executive Officer, Chief Operating Officer, Chief Scientific Officer, Chief Legal Officer and Chief Financial Officer shall each not be considered to be an Eligible Employee for purposes of the Plan.

(b) **Release Requirement.** In order to be eligible to receive benefits under the Plan, the employee also must execute a general waiver and release in substantially the form attached hereto as Exhibit A, Exhibit B or Exhibit C, as appropriate (the "***Release***"), within the applicable time period set forth therein, but in no event more than fifty (50) days following the Termination Date of the applicable Covered Termination, and such Release must become effective in accordance with its terms. The

Company, in its sole discretion, may modify the form of the Release to comply with applicable law. The Release may be incorporated into a termination agreement or other agreement with the employee.

(c) No Duplicative Benefits Provided Under Plan. This Plan does not supersede the terms of any Individual Severance Arrangement. Unless otherwise determined by the Plan Administrator in its discretion, if an employee is an Eligible Employee and otherwise eligible to receive severance benefits under this Plan that are of the same category and would otherwise duplicate the benefits available under the terms of any Individual Severance Arrangement ("***Duplicative Benefits***") such Eligible Employee will receive severance benefits under the Individual Severance Arrangement in lieu of any Plan benefits to the extent such benefits are Duplicative Benefits, and severance benefits will be provided under the Plan only to the extent, if any, that Plan benefits are not Duplicative Benefits.

(d) Exceptions to Benefit Entitlement. An employee who otherwise is an Eligible Employee will not receive benefits under the Plan in the following circumstances, as determined by the Plan Administrator in its sole discretion:

(1) The employee is terminated by the Company for any reason (including due to the employee's death or disability) or voluntarily terminates employment with the Company in any manner, and in either case, such termination does not constitute a Covered Termination. Voluntary terminations include, but are not limited to, resignation, retirement or failure to return from a leave of absence on the scheduled date.

(2) The employee voluntarily terminates employment with the Company in order to accept employment with another entity that is wholly or partly owned (directly or indirectly) by the Company or an Affiliate.

(3) The employee is offered an identical or substantially equivalent or comparable position with the Company or an Affiliate. For purposes of the foregoing, a "substantially equivalent or comparable position" is one that provides the employee substantially the same level of responsibility and compensation.

(4) The employee is offered immediate reemployment by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control in a "substantially equivalent or comparable position" as defined in Section 2(d)(3). For purposes of the foregoing, "immediate reemployment" means that the employee's employment with the successor to the Company or an Affiliate or the purchaser of its assets, as the case may be, results in uninterrupted employment such that the employee does not incur a lapse in pay or benefits as a result of the change in ownership of the Company or the sale of its assets. For the avoidance of doubt, an employee who becomes immediately reemployed as described in this Section 2(d)(4) by a successor to the Company or an Affiliate or by a purchaser of the Company's assets, as the case may be, following a Change in Control shall continue to be an Eligible Employee following the date of such reemployment.

(5) The employee is rehired by the Company or an Affiliate and recommences employment prior to the date benefits under the Plan are scheduled to commence.

Section 3. AMOUNT OF BENEFIT.

(a) Severance Benefit. Benefits under the Plan shall be provided to an Eligible Employee as follows, subject to any delay in payment that may be required by Section 5:

(1) Severance Pay. The Eligible Employee will be entitled to receive a single lump sum cash payment equal to (A) 50% of the Eligible Employee's Annual Base Salary, *plus* (B) an amount equal to the Eligible Employee's Target Bonus, pro-rated based on the number of days actually served in the calendar year during which the Termination Date occurs (the sum of (A) and (B), the "***Severance Pay***"). The Severance Pay will be payable to the Eligible Employee within ten (10) business days following the later of (i) the effective date of the Release, or (ii) the effective date of the Closing.

(2) Accelerated Vesting of Stock Awards. Effective as of the later of the effective date of the Release or the effective date of the Closing, to the extent not previously vested: (A) the vesting and exercisability of all outstanding stock options to purchase the Company's common stock that are held by the Eligible Employee on such date shall be accelerated in full, (B) any reacquisition or repurchase rights held by the Company in respect of common stock issued pursuant to any other stock award granted to the Eligible Employee by the Company shall lapse in full, and (C) the vesting of any other stock awards granted to the Eligible Employee by the Company, and any issuance of shares triggered by the vesting of such stock awards, shall be accelerated in full; provided, however, that the foregoing provisions shall not apply to stock awards issued under or held in any Qualified Plan. For purposes of determining the number of shares that will vest pursuant to the foregoing provision with respect to any performance based vesting award that has multiple vesting levels depending upon the level of performance, vesting acceleration shall occur with respect to the number of shares subject to the award as if the applicable performance criteria had been attained at a 100% level. In order to give effect to the intent of the foregoing provision, notwithstanding anything to the contrary set forth in the Eligible Employee's stock award agreements or the applicable equity incentive plan under which such stock award was granted that provides that any then unvested portion of the award will immediately expire upon the Eligible Employee's termination of service, the stock awards referred to in this Section 3(a)(2) shall remain outstanding after an Eligible Employee's Covered Termination to the extent necessary to give effect to the potential vesting acceleration in this Section 3(a)(2) (e.g., if an Eligible Employee's Covered Termination occurs prior to the Closing). Notwithstanding anything to the contrary set forth herein, the Eligible Employee's stock awards shall remain subject to the terms of the applicable Company plan and award documents under which such stock award was granted, including any provision for earlier termination of such stock awards upon a "corporate transaction," "change in control" or similar event under the terms of the applicable Company equity incentive plan or substantially equivalent provisions applicable to such stock option or stock award.

(3) Payment of Continued Group Health Plan Benefits.

(i) Provided that the Eligible Employee is a participant in the Company's group health plans as of immediately prior to the Covered Termination, if the Eligible Employee timely elects continued group health plan continuation coverage under COBRA with respect to such group health plans, the Company shall directly pay to the Company's group health care provider an amount equal to the COBRA premiums, less the amount the Eligible Employee would have had to pay to receive group health coverage for the Eligible Employee and the Eligible Employee's covered dependents based on the cost sharing levels in effect on the Eligible Employee's Termination Date (which for the avoidance of doubt the Eligible Employee shall be required to pay directly to the Company's group health care provider together with any administrative or additional costs due with respect to such COBRA coverage), for the Eligible Employee and the Eligible Employee's covered dependents under such plans during the period commencing on the Termination Date and ending upon the last day of the six (6) month period following the Covered Termination (the "***COBRA Payment Period***"). Upon the conclusion of such period of insurance premium payments made by the Company, the Eligible Employee will be responsible for the entire payment of premiums (or payment for the cost of coverage) required under

COBRA for the duration of the Eligible Employee's eligible COBRA coverage period. For purposes of this Section, (A) references to COBRA shall be deemed to refer also to analogous provisions of state law and (B) any applicable insurance premiums that are paid by the Company shall not include any amounts payable by the Eligible Employee under an Internal Revenue Code Section 125 health care reimbursement plan, which amounts, if any, are the Eligible Employee's sole responsibility.

(ii) Notwithstanding the foregoing, if at any time the Company determines, in its sole discretion, that it cannot provide the COBRA premium benefits without potentially incurring financial costs or penalties under applicable law (including, without limitation, Section 2716 of the Public Health Service Act), then in lieu of paying COBRA premiums on the Eligible Employee's behalf, the Company will instead pay the Eligible Employee on the last day of each remaining month of the COBRA Payment Period a fully taxable cash payment equal to the COBRA premium for that month, subject to applicable tax withholding (such amount, the "***Special Severance Payment***"), such Special Severance Payment to be made without regard to the Eligible Employee's election of COBRA coverage or payment of COBRA premiums and without regard to the Eligible Employee's continued eligibility for COBRA coverage during the COBRA Payment Period. Such Special Severance Payment shall end upon expiration of the COBRA Payment Period.

(b) Additional Benefits. Notwithstanding the foregoing, the Company may, in its sole discretion, provide benefits to employees who are not Eligible Employees ("***Non-Eligible Employees***") chosen by the Board, in its sole discretion, and the provision of any such benefits to a Non-Eligible Employee shall in no way obligate the Company to provide such benefits to any other Non-Eligible Employee, even if similarly situated. If benefits under the Plan are provided to a Non-Eligible Employee, references in the Plan to "Eligible Employee" (and similar references) shall be deemed to refer to such Non-Eligible Employee.

(c) Certain Reductions. The Company, in its sole discretion, shall have the authority to reduce an Eligible Employee's severance benefits, in whole or in part, by pay and benefits provided during a period following written notice of a plant closing or mass layoff, pay and benefits in lieu of such notice, or other similar benefits payable to the Eligible Employee by the Company or an Affiliate that become payable in connection with the Eligible Employee's termination of employment pursuant to (i) any applicable legal requirement, including, without limitation, the Worker Adjustment and Retraining Notification Act or any other similar state law, (ii) any Company policy or practice providing for the Eligible Employee to remain on the payroll for a limited period of time after being given notice of the termination of the Eligible Employee's employment, or (iii) any other severance benefit agreement or arrangement between the Company and the Eligible Employee, and the Plan Administrator shall so construe and implement the terms of the Plan, in each case to the extent compliant with Section 409A of the Code. Any such reductions that the Company determines to make pursuant to this Section 3(c) shall be made such that any benefit under the Plan shall be reduced solely by any similar type of benefit under such legal requirement, agreement, policy or practice (*i.e.*, any cash severance benefits under the Plan shall be reduced solely by any cash payments or severance benefits under such legal requirement, agreement, policy or practice, and any continued insurance benefits under the Plan shall be reduced solely by any continued insurance benefits under such legal requirement, agreement, policy or practice). The Company's decision to apply such reductions to the severance benefits of one Eligible Employee and the amount of such reductions shall in no way obligate the Company to apply the same reductions in the same amounts to the severance benefits of any other Eligible Employee, even if similarly situated. In the Company's sole discretion, such reductions may be applied on a retroactive basis, with severance benefits previously paid being re-characterized as payments pursuant to the Company's statutory obligation.

(d) Parachute Payments. The following provisions shall not supersede any provisions to the contrary provided under any Individual Severance Arrangement, if applicable:

(1) Any provision of the Plan to the contrary notwithstanding, if any payment or benefit an Eligible Employee would receive from the Company pursuant to the Plan or otherwise ("***Payment***") would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) but for this sentence, be subject to the excise tax imposed by Section 4999 of the Code (the "***Excise Tax***"), then such Payment will be equal to the Reduced Amount (defined below). The "***Reduced Amount***" shall be either (x) the largest portion of the Payment that would result in no portion of the Payment being subject to the Excise Tax or (y) the largest portion, up to and including the total, of the Payment, whichever amount, after taking into account all applicable federal, state and local employment taxes, income taxes, and the Excise Tax (all computed at the highest applicable marginal rate), results in the Eligible Employee's receipt, on an after-tax basis, of the greater economic benefit notwithstanding that all or some portion of the Payment may be subject to the Excise Tax. If a reduction in payments or benefits constituting "parachute payments" is necessary so that the Payment equals the Reduced Amount, reduction shall occur in the manner that results in the greatest economic benefit for the Eligible Employee. If more than one method of reduction will result in the same economic benefit, the items so reduced will be reduced pro rata.

(2) In the event it is subsequently determined by the Internal Revenue Service that some portion of the Reduced Amount as determined pursuant to clause (x) in the preceding paragraph is subject to the Excise Tax, the Eligible Employee agrees to promptly return to the Company a sufficient amount of the Payment so that no portion of the Reduced Amount is subject to the Excise Tax. For the avoidance of doubt, if the Reduced Amount is determined pursuant to clause (y) in the preceding paragraph, the Eligible Employee will have no obligation to return any portion of the Payment pursuant to the preceding sentence.

(3) Unless the Eligible Employee and the Company agree on an alternative accounting firm or law firm, the accounting firm engaged by the Company for general tax compliance purposes as of the day prior to the effective date of the Change in Control shall perform the foregoing calculations. If the accounting firm so engaged by the Company is serving as accountant or auditor for the individual, entity or group effecting the Change in Control, the Company shall appoint a nationally recognized accounting or law firm to make the determinations required hereunder. The Company shall bear all expenses with respect to the determinations by such accounting or law firm required to be made hereunder.

Section 4. RETURN OF COMPANY PROPERTY.

An Eligible Employee will not be entitled to any severance benefit under the Plan unless and until the Eligible Employee returns all Company Property. For this purpose, "Company Property" means all Company documents (and all copies thereof) and other Company property which the Eligible Employee had in his or her possession at any time, including, but not limited to, Company files, notes, drawings, records, plans, forecasts, reports, studies, analyses, proposals, agreements, financial information, research and development information, sales and marketing information, operational and personnel information, specifications, code, software, databases, computer-recorded information, tangible property and equipment (including, but not limited to, computers, facsimile machines, mobile telephones, servers), credit cards, entry cards, identification badges and keys; and any materials of any kind which contain or embody any proprietary or confidential information of the Company (and all reproductions thereof in whole or in part).

Section 5. TAX WITHHOLDING; OFFSET; SECTION 409A.

All payments under the Plan will be subject to applicable withholding for federal, state and local taxes. If an Eligible Employee is indebted to the Company on his or her termination date, the Company reserves the right to offset any severance payments under the Plan by the amount of such indebtedness. All severance benefits provided under the Plan are intended to satisfy the requirements for an exemption from application of Section 409A of the Code to the maximum extent that an exemption is available and any ambiguities herein shall be interpreted accordingly.

Notwithstanding anything to the contrary set forth herein, any payments and benefits provided under the Plan that constitute "deferred compensation" within the meaning of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively "***Section 409A***") shall not commence in connection with an Eligible Employee's termination of employment unless and until the Eligible Employee has also incurred a "separation from service," as such term is defined in Treasury Regulations Section 1.409A-1(h) ("***Separation from Service***"), unless the Company reasonably determines that such amounts may be provided to the Eligible Employee without causing the Eligible Employee to incur the adverse personal tax consequences under Section 409A.

It is intended that (i) each installment of any benefits payable under the Plan to an Eligible Employee be regarded as a separate "payment" for purposes of Treasury Regulations Section 1.409A-2(b)(2)(i), (ii) all payments of any such benefits under the Plan satisfy, to the greatest extent possible, the exemptions from the application of Section 409A provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9)(iii), and (iii) any such benefits consisting of COBRA premiums also satisfy, to the greatest extent possible, the exemption from the application of Section 409A provided under Treasury Regulations Section 1.409A-1(b)(9)(v). However, if the Company determines that any such benefits payable under the Plan constitute "deferred compensation" under Section 409A and the Eligible Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i), then, solely to the extent necessary to avoid the imposition of the adverse personal tax consequences under Section 409A, (A) the timing of such benefit payments shall be delayed until the earlier of (1) the date that is six (6) months and one (1) day after the Eligible Employee's Separation from Service and (2) the date of the Eligible Employee's death (such applicable date, the "***Delayed Initial Payment Date***"), and (B) the Company shall (1) pay the Eligible Employee a lump sum amount equal to the sum of the benefit payments that the Eligible Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the benefits had not been delayed pursuant to this paragraph and (2) commence paying the balance, if any, of the benefits in accordance with the applicable payment schedule.

In no event shall payment of any benefits under the Plan be made prior to an Eligible Employee's Termination Date or prior to the effective date of the Release. If the Company determines that any payments or benefits provided under the Plan constitute "deferred compensation" under Section 409A, and the Eligible Employee's Separation from Service occurs at a time during the calendar year when the Release could become effective in the calendar year following the calendar year in which the Eligible Employee's Separation from Service occurs, then regardless of when the Release is returned to the Company and becomes effective, the Release will not be deemed effective any earlier than the latest permitted effective date.

Section 6. REEMPLOYMENT.

In the event of an Eligible Employee's reemployment by the Company during the period of time in respect of which severance benefits pursuant to the Plan have been paid, the Company, in its sole and absolute discretion, may require such Eligible Employee to repay to the Company all or a portion of such severance benefits as a condition of reemployment.

Section 7. TRANSFER AND ASSIGNMENT.

The rights and obligations of an Eligible Employee under this Plan may not be transferred or assigned without the prior written consent of the Company. The Plan shall be binding upon any entity or person who is a successor by merger, acquisition, consolidation or otherwise to the business formerly carried on by the Company without regard to whether or not such entity or person actively assumes the obligations hereunder and without regard to whether or not a Change in Control occurs.

Section 8. RIGHT TO INTERPRET AND ADMINISTER PLAN; AMENDMENT AND TERMINATION.

(a) Interpretation and Administration. Prior to the Closing, the Board shall be the Plan Administrator and shall have the exclusive discretion and authority to establish rules, forms, and procedures for the administration of the Plan and to construe and interpret the Plan and to decide any and all questions of fact, interpretation, definition, computation or administration arising in connection with the operation of the Plan, including, but not limited to, the eligibility to participate in the Plan and amount of benefits paid under the Plan. The rules, interpretations, computations and other actions of the Board shall be binding and conclusive on all persons. Upon and after the Closing, the Plan will be interpreted and administered in good faith by the Representative who shall be the Plan Administrator during such period. All actions taken by the Representative in interpreting the terms of the Plan and administering the Plan upon and after the Closing will be final and binding on all Eligible Employees. Any references in this Plan to the "Board" or "Plan Administrator" with respect to periods following the Closing shall mean the Representative.

(b) Amendment. The Plan Administrator reserves the right to amend this Plan at any time in its discretion; *provided, however,* that any amendment of the Plan that would adversely affect a particular employee will not be effective as to such employee without his or her written consent if at the time of such amendment such employee previously has been terminated in a Covered Termination.

(c) Termination. The Plan will automatically terminate following satisfaction of all the Company's obligations under the Plan. The Plan may be earlier terminated at any time at the discretion of the Plan Administrator, provided, however, that no such discretionary termination by the Plan Administrator may be implemented with respect to any employee without his or her written consent if at such time the employee previously has been terminated in a Covered Termination.

Section 9. NO IMPLIED EMPLOYMENT CONTRACT.

The Plan shall not be deemed (i) to give any employee or other person any right to be retained in the employ of the Company or (ii) to interfere with the right of the Company to discharge any employee or other person at any time, with or without cause, which right is hereby reserved.

Section 10. LEGAL CONSTRUCTION.

This Plan is intended to be governed by and shall be construed in accordance with the Employee Retirement Income Security Act of 1974 ("***ERISA***") and, to the extent not preempted by ERISA, the laws of the Commonwealth of Pennsylvania.

Section 11. CLAIMS, INQUIRIES AND APPEALS.

(a) Applications for Benefits and Inquiries. Any application for benefits, inquiries about the Plan or inquiries about present or future rights under the Plan must be submitted to the Plan Administrator in writing by an applicant (or his or her authorized representative). The Plan Administrator is:

Aclaris Therapeutics, Inc.
Board of Directors
101 Lindenwood Drive, Suite 400
Malvern, PA 19355

(b) Denial of Claims. In the event that any application for benefits is denied in whole or in part, the Plan Administrator must provide the applicant with written or electronic notice of the denial of the application, and of the applicant's right to review the denial. Any electronic notice will comply with the regulations of the U.S. Department of Labor. The notice of denial will be set forth in a manner designed to be understood by the applicant and will include the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a description of any additional information or material that the Plan Administrator needs to complete the review and an explanation of why such information or material is necessary; and

(4) an explanation of the Plan's review procedures and the time limits applicable to such procedures, including a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA following a denial on review of the claim, as described in Section 11(d) below.

This notice of denial will be given to the applicant within ninety (90) days after the Plan Administrator receives the application, unless special circumstances require an extension of time, in which case, the Plan Administrator has up to an additional ninety (90) days for processing the application. If an extension of time for processing is required, written notice of the extension will be furnished to the applicant before the end of the initial ninety (90) day period.

This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the application.

(c) Request for a Review. Any person (or that person's authorized representative) for whom an application for benefits is denied, in whole or in part, may appeal the denial by submitting a request for a review to the Plan Administrator within sixty (60) days after the application is denied. A request for a review shall be in writing and shall be addressed to:

A request for review must set forth all of the grounds on which it is based, all facts in support of the request and any other matters that the applicant feels are pertinent. The applicant (or his or her representative) shall have the opportunity to submit (or the Plan Administrator may require the applicant to submit) written comments, documents, records, and other information relating to his or her claim. The applicant (or his or her representative) shall be provided, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim. The review shall take into account all comments, documents, records and other information submitted by the applicant (or his or her representative) relating to the claim, without regard to whether such information was submitted or considered in the initial benefit determination.

(d) Decision on Review. The Plan Administrator will act on each request for review within sixty (60) days after receipt of the request, unless special circumstances require an extension of time (not to exceed an additional sixty (60) days), for processing the request for a review. If an extension for review is required, written notice of the extension will be furnished to the applicant within the initial sixty (60) day period. This notice of extension will describe the special circumstances necessitating the additional time and the date by which the Plan Administrator is to render its decision on the review. The Plan Administrator will give prompt, written or electronic notice of its decision to the applicant. Any electronic notice will comply with the regulations of the U.S. Department of Labor. In the event that the Plan Administrator confirms the denial of the application for benefits in whole or in part, the notice will set forth, in a manner calculated to be understood by the applicant, the following:

(1) the specific reason or reasons for the denial;

(2) references to the specific Plan provisions upon which the denial is based;

(3) a statement that the applicant is entitled to receive, upon request and free of charge, reasonable access to, and copies of, all documents, records and other information relevant to his or her claim; and

(4) a statement of the applicant's right to bring a civil action under Section 502(a) of ERISA.

(e) Rules and Procedures. The Plan Administrator will establish rules and procedures, consistent with the Plan and with ERISA, as necessary and appropriate in carrying out its responsibilities in reviewing benefit claims. The Plan Administrator may require an applicant who wishes to submit additional information in connection with an appeal from the denial of benefits to do so at the applicant's own expense.

(f) Exhaustion of Remedies. No legal action for benefits under the Plan may be brought until the applicant (i) has submitted a written application for benefits in accordance with the procedures described by Section 11(a) above, (ii) has been notified by the Plan Administrator that the application is denied, (iii) has filed a written request for a review of the application in accordance with the appeal procedure described in Section 11(c) above, and (iv) has been notified that the Plan Administrator has denied the appeal. Notwithstanding the foregoing, if the Plan Administrator does not respond to an

Eligible Employee's claim or appeal within the relevant time limits specified in this Section 11, the Eligible Employee may bring legal action for benefits under the Plan pursuant to Section 502(a) of ERISA.

Section 12. BASIS OF PAYMENTS TO AND FROM PLAN.

The Plan shall be unfunded, and all cash payments under the Plan shall be paid only from the general assets of the Company.

Section 13. OTHER PLAN INFORMATION.

(a) Employer and Plan Identification Numbers. The Employer Identification Number assigned to the Company (which is the "Plan Sponsor" as that term is used in ERISA) by the Internal Revenue Service is 46-0571712. The Plan Number assigned to the Plan by the Plan Sponsor pursuant to the instructions of the Internal Revenue Service is [___].

(b) Ending Date for Plan's Fiscal Year. The date of the end of the fiscal year for the purpose of maintaining the Plan's records is December 31.

(c) Agent for the Service of Legal Process. The agent for the service of legal process with respect to the Plan is:

Aclaris Therapeutics, Inc.
101 Lindenwood Drive, Suite 400
Malvern, PA 19355

In addition, service of legal process may be made upon the Plan Administrator.

(d) Plan Sponsor. The "Plan Sponsor" is:

Aclaris Therapeutics, Inc.
101 Lindenwood Drive, Suite 400
Malvern, PA 19355
(484) 324-7933

(e) Plan Administrator. The Plan Administrator is the Board prior to the Closing and the Representative upon and following the Closing. The Plan Administrator's contact information is:

Aclaris Therapeutics, Inc.
Board of Directors or Representative
101 Lindenwood Drive, Suite 400
Malvern, PA 19355
(484) 324-7933

The Plan Administrator is the named fiduciary charged with the responsibility for administering the Plan.

Section 14. STATEMENT OF ERISA RIGHTS.

Participants in this Plan (which is a welfare benefit plan sponsored by Aclaris Therapeutics, Inc.) are entitled to certain rights and protections under ERISA. If you are an Eligible Employee, you are considered a participant in the Plan and, under ERISA, you are entitled to:

(a) Receive Information About Your Plan and Benefits

(1) Examine, without charge, at the Plan Administrator's office and at other specified locations, such as worksites, all documents governing the Plan and a copy of the latest annual report (Form 5500 Series), if applicable, filed by the Plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration;

(2) Obtain, upon written request to the Plan Administrator, copies of documents governing the operation of the Plan and copies of the latest annual report (Form 5500 Series), if applicable, and an updated (as necessary) Summary Plan Description. The Plan Administrator may make a reasonable charge for the copies; and

(3) Receive a summary of the Plan's annual financial report, if applicable. The Plan Administrator is required by law to furnish each Eligible Employee with a copy of this summary annual report.

(b) Prudent Actions by Plan Fiduciaries. In addition to creating rights for Eligible Employees, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate the Plan, called "fiduciaries" of the Plan, have a duty to do so prudently and in the interest of you and other Eligible Employees and beneficiaries. No one, including your employer, your union or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a Plan benefit or exercising your rights under ERISA.

(c) Enforce Your Rights. If your claim for a Plan benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of Plan documents or the latest annual report from the Plan, if applicable, and do not receive them within thirty (30) days, you may file suit in a Federal court. In such a case, the court may require the Plan Administrator to provide the materials and pay you up to $110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Plan Administrator.

If you have a claim for benefits which is denied or ignored, in whole or in part, you may file suit in a state or Federal court.

If you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful, the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

(d) Assistance with Your Questions. If you have any questions about the Plan, you should contact the Plan Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Plan Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Employee Benefits Security Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Employee Benefits Security Administration.

EXHIBIT A

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the Aclaris Therapeutics, Inc. Change in Control Severance Benefit Plan (the "*Plan*").

I understand that this Release Agreement (the "***Release***"), together with the Plan, constitutes the complete, final and exclusive embodiment of the entire agreement between Aclaris Therapeutics, Inc. (the "***Company***"), Affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an Affiliate of the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Plan.

I hereby confirm my obligations under my Confidentiality and Invention Rights, Non-competition and Non-solicitation Agreement with the Company and/or an Affiliate of the Company.

In consideration of the severance benefits and other consideration provided to me under the Plan that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its Affiliates, and their parents, subsidiaries, successors, predecessors and affiliates, and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns, from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "***Released Claims***"). The Released Claims include, but are not limited to: (a) all claims arising out of or in any way related to my employment with the Company and its Affiliates, or their affiliates, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and its Affiliates, or their affiliates; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including but not limited to claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990 (as amended), the federal Age Discrimination in Employment Act (as amended) ("***ADEA***"), the federal Family and Medical Leave Act, the federal Employee Retirement Income Security Act of 1974 (as amended), the Pennsylvania Human Relations Act, the Pennsylvania Wage Payment and Collection Law, the Pennsylvania Whistleblower Law and the Pennsylvania Equal Pay Law.

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or its Affiliates to which I am a party; the charter, bylaws, or operating agreements of the Company or its Affiliates; or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, or any other federal, state or local government agency or commission (collectively, the "***Government Agencies***"). This Release does not limit my ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be

conducted by any Government Agencies, including providing documents or other information, without notice to the Company. While this Release does not limit my right to receive an award for information provided to the Securities and Exchange Commission, I understand and agree that, to maximum extent permitted by law, I am otherwise waiving any and all rights I may have to individual relief based on any claims that I have released and any rights that I have waived by signing this Release. I hereby represent and warrant that, other than the claims identified in this paragraph, I am not aware of any claims I have or might have that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA, and that the consideration given under the Plan for the waiver and release in this paragraph is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release do not apply to any rights or claims that may arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not do so); (c) I have twenty-one (21) days to consider this Release (although I may choose voluntarily to sign this Release earlier); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice to an officer of the Company; and (e) this Release shall not be effective until the date upon which the revocation period has expired, which shall be the eighth day after I sign this Release provided I have not revoked it.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than twenty-one (21) days following the date it is provided to me or such other date as specified by the Company.

ELIGIBLE EMPLOYEE

Printed Name: _____

Signature: _____

Date: _____

EXHIBIT B

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the Aclaris Therapeutics, Inc. Change in Control Severance Benefit Plan (the *"Plan"*).

I understand that this Release Agreement (the "***Release***"), together with the Plan, constitutes the complete, final and exclusive embodiment of the entire agreement between the Aclaris Therapeutics, Inc. (the "***Company***"), Affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an Affiliate of the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Plan.

I hereby confirm my obligations under my Confidentiality and Invention Rights, Non-competition and Non-solicitation Agreement with the Company and/or an affiliate of the Company.

In consideration of the severance benefits and other consideration provided to me under the Plan that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its Affiliates, and their parents, subsidiaries, successors, predecessors and affiliates, and its and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns, from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "***Released Claims***"). The Released Claims include, but are not limited to: (a) all claims arising out of or in any way related to my employment with the Company and its Affiliates, or their affiliates, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and its Affiliates, or their affiliates; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including but not limited to claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990 (as amended), the federal Age Discrimination in Employment Act (as amended) ("***ADEA***"), the federal Family and Medical Leave Act, the federal Employee Retirement Income Security Act of 1974 (as amended), the Pennsylvania Human Relations Act, the Pennsylvania Wage Payment and Collection Law, the Pennsylvania Whistleblower Law and the Pennsylvania Equal Pay Law.

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or its Affiliates to which I am a party; the charter, bylaws, or operating agreements of the Company or its Affiliates; or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, or any other federal, state or local government agency or commission (collectively, the "***Government Agencies***"). This Release does not limit my ability to communicate with any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agencies, including providing documents or other information, without

notice to the Company. While this Release does not limit my right to receive an award for information provided to the Securities and Exchange Commission, I understand and agree that, to maximum extent permitted by law, I am otherwise waiving any and all rights I may have to individual relief based on any claims that I have released and any rights that I have waived by signing this Release. I hereby represent and warrant that, other than the claims identified in this paragraph, I am not aware of any claims I have or might have that are not included in the Released Claims.

I acknowledge that I am knowingly and voluntarily waiving and releasing any rights I may have under the ADEA, and that the consideration given under the Plan for the waiver and release in this paragraph is in addition to anything of value to which I was already entitled. I further acknowledge that I have been advised by this writing, as required by the ADEA, that: (a) my waiver and release do not apply to any rights or claims that may arise after the date I sign this Release; (b) I should consult with an attorney prior to signing this Release (although I may choose voluntarily not to do so); (c) I have forty-five (45) days to consider this Release (although I may choose voluntarily to sign this Release earlier); (d) I have seven (7) days following the date I sign this Release to revoke the Release by providing written notice to an officer of the Company; (e) this Release shall not be effective until the date upon which the revocation period has expired, which shall be the eighth day after I sign this Release provided I have not revoked it; and (f) I have received with this Release all of the information required by the ADEA, including without limitation a detailed list of the job titles and ages of all employees who were terminated in this group termination and the ages of all employees of the Company in the same job classification or organizational unit who were not terminated.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than forty-five (45) days following the date it is provided to me or such other date as specified by the Company.

ELIGIBLE EMPLOYEE

Printed Name: _____

Signature: _____

Date: _____

EXHIBIT C

RELEASE AGREEMENT

I understand and agree completely to the terms set forth in the Aclaris Therapeutics, Inc. Change in Control Severance Benefit Plan (the *"Plan"*).

I understand that this Release Agreement (the "*Release*"), together with the Plan, constitutes the complete, final and exclusive embodiment of the entire agreement between Aclaris Therapeutics, Inc. (the "***Company***"), Affiliates of the Company and me with regard to the subject matter hereof. I am not relying on any promise or representation by the Company or an Affiliate of the Company that is not expressly stated therein. Certain capitalized terms used in this Release are defined in the Plan.

I hereby confirm my obligations under my Confidentiality and Invention Rights, Non-competition and Non-solicitation Agreement with the Company and/or an Affiliate of the Company.

In consideration of the severance benefits and other consideration provided to me under the Plan that I am not otherwise entitled to receive, I hereby generally and completely release the Company and its Affiliates, and their parents, subsidiaries, successors, predecessors and affiliates, and its and their current and former partners, members, directors, officers, employees, stockholders, shareholders, agents, attorneys, predecessors, successors, insurers, affiliates and assigns, from any and all claims, liabilities and obligations, both known and unknown, that arise out of or are in any way related to events, acts, conduct, or omissions occurring at any time prior to and including the date I sign this Release (collectively, the "Released Claims"). The Released Claims include, but are not limited to: (a) all claims arising out of or in any way related to my employment with the Company and its Affiliates, or their affiliates, or the termination of that employment; (b) all claims related to my compensation or benefits, including salary, bonuses, commissions, vacation pay, expense reimbursements, severance pay, fringe benefits, stock, stock options, or any other ownership, equity, or profits interests in the Company and its Affiliates, or their affiliates; (c) all claims for breach of contract, wrongful termination, and breach of the implied covenant of good faith and fair dealing; (d) all tort claims, including claims for fraud, defamation, emotional distress, and discharge in violation of public policy; and (e) all federal, state, and local statutory claims, including but not limited to claims for discrimination, harassment, retaliation, attorneys' fees, or other claims arising under the federal Civil Rights Act of 1964 (as amended), the federal Americans with Disabilities Act of 1990 (as amended), the federal Family and Medical Leave Act, the federal Employee Retirement Income Security Act of 1974 (as amended), the Pennsylvania Human Relations Act, the Pennsylvania Wage Payment and Collection Law, the Pennsylvania Whistleblower Law and the Pennsylvania Equal Pay Law.

Notwithstanding the foregoing, I understand that the following rights or claims are not included in the Released Claims: (a) any rights or claims for indemnification I may have pursuant to any written indemnification agreement with the Company or its Affiliates to which I am a party; the charter, bylaws, or operating agreements of the Company or its Affiliates; or under applicable law; or (b) any rights that cannot be waived as a matter of law. In addition, I understand that nothing in this Release prevents me from filing, cooperating with, or participating in any proceeding before the Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the Securities and Exchange Commission, or any other federal, state or local government agency or commission (collectively, the "***Government Agencies***"). This Release does not limit my ability to communicate with

any Government Agencies or otherwise participate in any investigation or proceeding that may be conducted by any Government Agencies, including providing documents or other information, without notice to the Company. While this Release does not limit my right to receive an award for information provided to the Securities and Exchange Commission, I understand and agree that, to maximum extent permitted by law, I am otherwise waiving any and all rights I may have to individual relief based on any claims that I have released and any rights that I have waived by signing this Release. I hereby represent and warrant that, other than the claims identified in this paragraph, I am not aware of any claims I have or might have that are not included in the Released Claims.

I hereby represent that I have been paid all compensation owed and for all hours worked; I have received all the leave and leave benefits and protections for which I am eligible pursuant to the Family and Medical Leave Act or otherwise; and I have not suffered any on-the-job injury for which I have not already filed a workers' compensation claim.

I acknowledge that to become effective, I must sign and return this Release to the Company so that it is received not later than fourteen (14) days following the date it is provided to me or such other date as specified by the Company.

ELIGIBLE EMPLOYEE

Printed Name: _____

Signature: _____

Date: _____

ACLARIS THERAPEUTICS, INC.

FIRST AMENDMENT TO
CHANGE IN CONTROL SEVERANCE BENEFIT PLAN

WHEREAS, Aclaris Therapeutics, Inc., a Delaware Corporation (the "***Company***"), has adopted and maintains the "Aclaris Therapeutics, Inc. Change in Control Severance Benefit Plan" (the "***Plan***") for the benefit of "Eligible Employees," as that term is defined in the Plan; and

WHEREAS, the Plan Administrator (as defined in the Plan) desires to amend the requirements to be an "Eligible Employee."

NOW THEREFORE, pursuant to the power of amendment contained in Section 8(b) of the Plan, the Plan is hereby amended as follows:

1. The first sentence of Section 2(a) of the Plan is hereby deleted in its entirety and replaced with the following, which shall be effective for employees of the Company whose employment commences after October 2, 2019:

> "An employee of the Company is eligible to participate in the Plan if (i) the employee is an officer or other employee who reports directly to the Chief Executive Officer of the Company on any date within the Covered Period; (ii) the Board has designated such employee as eligible to participate in the Plan; (iii) such employee's employment with the Company terminates due to a Covered Termination; and (iv) such employee meets the other Plan eligibility requirements set forth in this Section 2 and the Plan.

2. Each reference in the Plan to "101 Lindenwood Drive, Suite 400, Malvern, PA 19355" is hereby deleted in its entirety and replaced with the following:

> "640 Lee Road, Suite 200
> Wayne, PA 19087"

* * * * *

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. 333-238079, 333-230614, 333-223922, 333-220149, 333-216703, 333-210379 and 333-207434) of Aclaris Therapeutics, Inc. of our report dated February 25, 2021 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
February 25, 2021

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, 2021

/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, 2021

/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, 2020 (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 2021.

/s/ Neal Walker	/s/ Frank Ruffo
Neal Walker	Frank Ruffo
President & Chief Executive Officer	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.