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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, 2021 **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, 2021, 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 $914.5 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, 2022, 61,275,033 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 2022 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.

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 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 zunsemetinib, an inhibitor of the mitogen-activated protein kinase-activated protein kinase 2, or MK2, signaling pathway, ATI-1777, a topical "soft" Janus kinase, or JAK, inhibitor, and ATI-2138, an inhibitor of interleukin-2-inducible T cell kinase, or ITK. We also earn revenue from Confluence's provision of contract research services to third parties.

Our Drug Candidates

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				
Zunsemetinib	MK2 inhibitor	Oral	Rheumatoid arthritis (moderate to severe)	Phase 2
			Psoriatic arthritis (moderate to severe)	Phase 2*
			Hidradenitis suppurativa (moderate to severe)	Phase 2
ATI-1777	"Soft" JAK 1/3 inhibitor	Topical	Atopic dermatitis (moderate to severe)	Phase 2
ATI-2138	ITK/TXK/JAK3 inhibitor	Oral	T cell-mediated autoimmune diseases	Phase 1
Gut-Biased Program	JAK inhibitor	Oral	Inflammatory bowel disease	Discovery
Oncology				
ATI-2231	MK2 inhibitor	Oral	Metastatic breast cancer	Preclinical
			Pancreatic cancer	

* We plan to progress this indication directly into Phase 2.

Clinical Programs

Zunsemetinib, an Investigational Oral MK2 Inhibitor

We submitted an Investigational New Drug Application, or IND, in April 2019 for zunsemetinib, 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, IL17 and other essential pathogenic signals in chronic immuno-inflammatory diseases, as well as in oncology. As an oral drug candidate, we are developing zunsemetinib as a potential alternative to injectable anti-TNF/IL1/IL6 biologics and JAK inhibitors for treating certain immuno-inflammatory diseases. Zunsemetinib has been adopted as the nonproprietary name for ATI-450.

We initiated a Phase 1 single (at 10 mg, 30 mg, 50 mg and 100 mg doses) and multiple ascending (at 10 mg, 30 mg and 50 mg doses) dose clinical trial evaluating zunsemetinib in 77 healthy subjects in August 2019 (ATI-450-PKPD-101). Final data from this trial demonstrated that zunsemetinib resulted in marked inhibition of TNFα, IL1β, IL8 and IL6. We also observed that zunsemetinib 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. Zunsemetinib was generally well-tolerated at all doses tested in the trial. The most common adverse events (reported by 2 or more subjects who received zunsemetinib) were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain and nausea.

Zunsemetinib was also evaluated at 80 mg and 120 mg doses twice daily in a second Phase 1 clinical trial in healthy subjects (ATI-450-PKPD-102). Final 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 zunsemetinib relative to doses tested in the first Phase 1 trial. 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 zunsemetinib) were headache, dizziness, nausea, parasthesia and, in the post-dosing follow-up period of the trial, dry skin. These adverse events were all mild in severity.

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 zunsemetinib in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-201). In the trial, which consisted of a 12-week treatment period and a 4-week follow-up period, 19 subjects were randomized in a 3:1 ratio and received either zunsemetinib at 50 mg twice daily or placebo, in combination with methotrexate, for 12 weeks.

The final per-protocol analysis, which consisted of the 17 subjects who completed the treatment period (15 in the treatment arm and two in the placebo arm), showed that zunsemetinib 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. Zunsemetinib 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, and ventricular extrasystoles, all of which were determined to be unrelated to treatment except for one UTI. Two subjects withdrew from the trial during the treatment period, one in the treatment arm and one in the placebo arm. The subject in the treatment arm withdrew due to an elevated creatine phosphokinase, or CPK, level, which was determined by the site investigator to be treatment-related; this subject also had palpitations and ventricular extrasystoles, which were unrelated to the trial medication. The subject in the placebo arm withdrew as a result of prohibited medication needed to treat muscle strain. There was also one non-treatment-related serious adverse event (COVID-19) reported in the 4-week follow-up period of the trial in a subject who was no longer receiving treatment; the subject withdrew during the 4-week follow-up period of the trial.

A final analysis, which consisted of the 17 subjects, 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 treatment 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.

In December 2021, we initiated study activities in a Phase 2b randomized, multicenter, double-blind, parallel group, placebo-controlled, dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-202). This trial will consist of a 12-week treatment period and a 30-day follow-up period, and currently seeks to enroll approximately 195 subjects in the United States and in multiple countries in Europe. The primary endpoint is the proportion of subjects achieving ACR20 at week 12. We anticipate increasing the size of the patient population to approximately 240 subjects and expect topline data in 2023.

Moderate to Severe Hidradenitis Suppurativa

In December 2021, we initiated study activities in a Phase 2a, randomized, multicenter, double-blind, placebo-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib (50 mg twice daily) in subjects with moderate to severe hidradenitis suppurativa (ATI-450-HS-201). This trial will consist of a 12-week treatment period and a 30-day follow-up period, and will seek to enroll approximately 70 subjects in the United States. The primary endpoint is the change in inflammatory nodule and abscess count at week 12. We expect topline data in the first half of 2023.

Moderate to Severe Psoriatic Arthritis

We plan to progress zunsemetinib (50 mg twice daily) into a Phase 2a trial in subjects with moderate to severe psoriatic arthritis in the first half of 2022, with topline data expected in the first half of 2023 (ATI-450-PsA-201).

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). In the trial, which consisted of a 4-week treatment period and a 2-week follow-up period during which no treatment was given, 50 subjects with moderate to severe atopic dermatitis were randomized in a 1:1 ratio into one of two arms: ATI-1777 topical solution 2.0% w/w or vehicle applied twice daily. In June 2021, we announced that the trial achieved its primary endpoint, which was the percent change from baseline in the modified Eczema Area and Severity Index, or mEASI, score at week 4, with a high degree of statistical significance ($p<0.001$) (one-sided p-value), which corresponded to a 74.4% reduction in mEASI score from baseline at week 4 in subjects applying ATI-1777 compared to a 41.4% reduction in subjects applying vehicle. The final data was based on the full analysis set, or FAS, which was comprised of 48 subjects randomized and documented to have received at least one dose of trial medication. Positive trends in favor of ATI-1777 were observed in key secondary efficacy endpoints, such as improvement in itch, percent of mEASI-50 responders, investigator's global assessment responder analysis, and reduction in body surface area impacted by disease. In addition, the FAS analysis also showed positive trends in favor of ATI-1777 in percent of mEASI-75 responders (65.2% for ATI-1777 compared to 24.0% for vehicle) and mEASI-90 responders (30.4% for ATI-1777 compared to 20.0% for vehicle). These secondary efficacy endpoints were not powered for statistical significance. Based on an analysis of pharmacokinetic plasma samples in the ATI-1777 arm at multiple timepoints, minimal systemic exposure was observed which supports a "soft" topical JAK inhibitor approach.

ATI-1777 was generally well tolerated. No serious adverse events were reported. The most common adverse events (reported in at least 2 subjects in the trial) were increased blood CPK levels and headache in subjects in the ATI-1777 arm and urinary tract infection (one in each of the ATI-1777 and the vehicle arm); none of these adverse events in the ATI-1777 arm were determined by the clinical trial investigators to be related to ATI-1777. One treatment-related adverse event, application site pruritus, was reported in one subject in the ATI-1777 arm.

Based on the results observed in the Phase 2a trial, we intend to progress ATI-1777 into a Phase 2b trial in moderate to severe atopic dermatitis in the first half of 2022. In this trial, we plan to explore multiple concentrations of twice daily treatment with ATI-1777 and a single concentration of once daily treatment with ATI-1777, in patients 12 years and older. We expect topline data in the first half of 2023.

ATI-2138, an Investigational Oral ITJ Inhibitor

We are developing ATI-2138, an investigational oral ITK/TXK/JAK3, or ITJ, inhibitor compound, as a potential treatment for T cell-mediated autoimmune diseases. The ITJ compound interrupts T cell signaling through the combined inhibition of ITK/TXK/JAK3 pathways in lymphocytes. We submitted an IND for ATI-2138 for the treatment of psoriasis in October 2021, which was allowed by the FDA in November 2021.

In December 2021, we initiated a Phase 1 randomized, observer-blind, placebo-controlled, single ascending dose trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-2138 in healthy subjects (ATI-2138-PKPD-101). We expect topline data in 2022.

If the Phase 1 SAD trial is successful, we currently plan to initiate a two-week Phase 1 multiple ascending dose trial of ATI-2138 in subjects with psoriasis in 2022, with topline data expected in the first half of 2023. We are also currently exploring alternative indications to the planned indication that are relevant to the mechanism of action which may impact the trial design and require the submission of additional INDs to different reviewing divisions of the FDA.

Preclinical Programs

ATI-2231, an Investigational Oral MK2 Inhibitor

We are exploring the use of ATI-2231, an investigational oral MK2 inhibitor compound designed to have a long half-life, as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer. IND-enabling studies are currently underway. We expect to submit an IND for ATI-2231 by the end of 2022. If allowed, we expect to progress ATI-2231 into the clinic in 2023. We are currently evaluating the clinical development program for this asset, which may include a collaboration with a third party.

Discovery Programs

We are developing oral gut-biased JAK inhibitors with limited systemic exposure as potential treatments for inflammatory bowel disease. In addition, we are engaged in research to identify brain penetrant kinase inhibitor candidates as potential treatments for neurodegenerative diseases.

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 zunsemetinib as a potential treatment for immuno-inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis and hidradenitis suppurativa, there are several different types of therapies in the market. Medications for the treatment of rheumatoid arthritis and psoriatic 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. DMARDs include (i) conventional synthetic DMARDs, such as methotrexate, sulfasalazine, leflunomide and hydroxychloroquine, (ii) biologic DMARDs (monoclonal antibodies which inhibit targets such as TNFα, IL1β, IL6, IL17 and costimulatory signaling mechanisms), and (iii) targeted synthetic DMARDs such as JAK inhibitors. Hidradenitis suppurativa is currently treated with antibiotics, corticosteroids and surgery, as well as anti-TNF therapy. Drugs for the treatment of immuno-inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis and hidradenitis suppurativa are produced and sold, or are approved

for marketing, by large pharmaceutical companies, including AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Pfizer, Novartis and Roche. 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 zunsemetinib, if approved, for the treatment of immuno-inflammatory diseases.

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, or are approved for marketing, by large pharmaceutical companies, including AbbVie, Incyte, LEO Pharma A/S, Pfizer, and Sanofi and Regeneron Pharmaceuticals, Inc. In addition, we are aware of a number of companies including large pharmaceutical companies, such as Eli Lilly, Novartis, LEO Pharma A/S, Pfizer and Dermavant Sciences 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 zunsemetinib, 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 issued U.S. patents and issued patents and pending applications in the European Union and other foreign countries directed to zunsemetinib 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. Further, we own numerous Patent Cooperation Treaty, or PCT, applications directed to certain methods of using zunsemetinib, methods of manufacturing zunsemetinib and crystal forms of zunsemetinib, which, if issued, would each expire in 2041, subject to any applicable adjustment or extension. We also own a PCT application directed to second generation MK2 inhibitors, such as ATI-2231, and methods of use, which, if issued, would expire in 2040, 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 2042, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own one U.S. patent and pending applications in the U.S., 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 a PCT application directed to crystal forms of ATI-1777 and provisional applications directed to methods of using ATI-1777 and topical formulations, which, if issued, would expire in 2041 and 2042, respectively, 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. For example, we own one U.S. patent and 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/or 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.

Under the Confluence Agreement, we 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 drugs 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 would expect to 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, as well as safety reporting. An IRB for each site 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, 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. 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 sponsor communications on the subject of off-label use.

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. In addition, FDA regulations and guidance are often issued revised or reinterpreted by the agency in ways that may significantly affect our business and our drug candidates. It is impossible to predict whether legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be issued or changed or what the impact of such changes, if any, may be.

Non-patent Exclusivity

The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to obtain approval of an NDA for a new chemical entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. If market exclusivity is granted for an NCE, during the exclusivity period, the FDA may not accept for review or approve an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement to one of the patents listed with the FDA by the innovator NDA holder.

The FDCA also provides three years of marketing exclusivity for an NDA, or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example new indications, dosages, dosage forms or strengths of an existing drug. This three-year exclusivity covers only the conditions associated with the new clinical investigations and prohibits the FDA from approving an ANDA or a 505(b)(2) NDA submitted by another company with overlapping conditions associated with the new clinical investigations for the three-year period. Clinical investigation exclusivity does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or approval of an NDA for the same drug. However, an applicant submitting an NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Regulation Outside of the United States

Even if we obtain FDA approval for a drug candidate, we must obtain approval by the comparable regulatory authorities of countries outside of the United States before we can commence clinical trials in such countries, and our potential third-party partners must obtain approval of the regulators of such countries or economic areas, such as the

European Union, before they may market any of our drug candidates in those countries or areas. The approval process and requirements governing the conduct of clinical trials, product licensing and promotion, pricing and reimbursement vary greatly by geographic region, and the time may be longer or shorter than that required for FDA approval.

In the European Economic Area, or EEA, which is composed of the 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, NCEs 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 an NCE, 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), other health care professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as information regarding ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties for "knowing failures." Certain states also mandate implementation of compliance programs, impose restrictions on drug manufacturer marketing practices, require registration of certain employees engaged in marketing activities in the

location, and/or require the tracking and reporting of gifts, compensation and other remuneration to health care professionals, including 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 have been executive branch, 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 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 June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed 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 possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges 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 and the Infrastructure Investment and Jobs Act, will stay in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022, unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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.

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 concurrently released a final rule and guidance in September 2020 providing pathways 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 until January 1, 2023. 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. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinds the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. 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. Further coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products which receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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, 2021, we had 77 total employees, of which 72 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, zunsemetinib.
- 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 $90.9 million and $51.0 million for the years ended December 31, 2021 and 2020, respectively. As of December 31, 2021, we had an accumulated deficit of $595.4 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 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 zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and other immuno-inflammatory diseases, ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, and ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases;
- continue to develop our preclinical drug candidates, including ATI-2231;
- 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. We also expect to add additional personnel to support our operational plans and strategic direction.

As of December 31, 2021, we had cash, cash equivalents and marketable securities of $225.7 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
- our ability to earn revenue from licenses to, or partnerships or other arrangements with, third parties.

We will require additional capital to complete the clinical development of zunsemetinib, ATI-1777 and ATI-2138, 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 could be forced to curtail our planned operations.

Our business is dependent on the successful development of our drug candidate, zunsemetinib.

Our pipeline includes zunsemetinib, our investigational oral, novel, selective MK2 inhibitor compound, which we are developing as a potential treatment for moderate to severe rheumatoid arthritis and 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, zunsemetinib.

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, our stockholders' ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of holders of our common stock. 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 undertaking preclinical studies and conducting clinical trials, drug discovery, acquiring new drug candidates and related intellectual property, and raising capital. 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, staggered work schedules for lab personnel and other alternative work arrangements for 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 have encountered some delays due to staffing shortages as a result of COVID-19 infections, and should they continue to experience disruptions or experience more significant disruptions, such as temporary closures, suspension of services or staffing shortages, 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.

The spread of COVID-19 and its variants, 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. In addition, a recession or market correction, inflation or other negative global economic conditions 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 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 spread of the disease, the introduction of new variants, the duration of the pandemic, 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 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.

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 zunsemetinib, 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.

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, 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 currently conduct and may in the future conduct clinical trials for our drug candidates outside the United States. The FDA, EMA or comparable foreign regulatory authorities may not accept data from such trials, and doing so subjects us to the risk that clinical development of our drug candidates may be adversely affected by changes in local and regional political and economic conditions.

We currently conduct and may in the future conduct clinical trials for our drug candidates outside the United States. The acceptance of trial data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. Such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any comparable regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our drug candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

In particular, we may enroll patients in our Phase 2b trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis in multiple countries in Europe, including Ukraine. Any escalation of political tensions, economic

instability, military activity or civil hostilities in Ukraine could disrupt our ability to conduct such trial, or delay or adversely affect the timeliness of such trial. This could result in the need for alternative trial sites, which could be costly and time-consuming and delay the clinical development of zunsemetinib.

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, in addition to our in-house capabilities. 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 zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and other immuno-inflammatory diseases, ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases and ATI-2231 as a potential treatment for oncology. 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 zunsemetinib as a potential treatment for immuno-inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis and hidradenitis suppurativa, there are several different types of therapies in the market. Medications for the treatment of rheumatoid arthritis and psoriatic 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. DMARDs include (i) conventional synthetic DMARDs, such as methotrexate, sulfasalazine, leflunomide and hydroxychloroquine, (ii) biologic DMARDs (monoclonal antibodies which inhibit targets such as TNFα, IL1β, IL6, IL17 and costimulatory signaling mechanisms), and (iii) targeted synthetic DMARDs such as JAK inhibitors. Hidradenitis suppurativa is currently treated with antibiotics, corticosteroids and surgery, as well as anti-TNF therapy. Drugs for the treatment of immuno-inflammatory diseases such as rheumatoid arthritis, psoriatic arthritis and hidradenitis suppurativa are produced and sold, or are approved for marketing, by large pharmaceutical companies, including AbbVie, Amgen, Bristol Myers Squibb, Eli Lilly, Johnson & Johnson, Pfizer, Novartis and Roche. 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 zunsemetinib, if approved, for the treatment of immuno-inflammatory diseases.

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, or are approved for marketing, by large pharmaceutical companies, including AbbVie, Incyte, LEO Pharma A/S, Pfizer, and Sanofi and Regeneron Pharmaceuticals, Inc. In addition, we are aware of a number of companies including large pharmaceutical companies, such as Eli Lilly, Novartis, LEO Pharma A/S, Pfizer and Dermavant Sciences 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. Further, coverage policies and third-party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products which receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

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 zunsemetinib expire in 2034. We currently do not have any patents issued directed to ATI-2231, but any claims that may issue would expire in 2040. Our issued U.S. patent covering ATI-1777 expires in 2038. Our issued U.S. patent directed to ATI-2138 expires in 2039. 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, zunsemetinib is currently covered by patents and applications in the United States, European Union and other foreign markets. While we have issued U.S. patents directed to ATI-1777 and ATI-2138, we do not currently have any patents for such drug candidates in the European Union or other foreign markets; rather, we have pending applications in the European Union and other foreign markets directed to each of ATI-1777 and ATI-2138. Currently, we do not have any issued patents directed to ATI-2231, but we have a pending PCT application.

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 us or 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 we or 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 we or they are able to, it may result in the reduction of revenue we earn from such partner as a result of payment obligations 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 drug candidates can be challenged by competitors.

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. 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. Litigation or other proceedings to enforce or defend intellectual property rights are often very complex in nature, may be expensive and time-consuming, may divert our management's attention from our core business, and may result in unfavorable results that could limit our ability to prevent third parties from competing with our drug candidates, if approved. 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 zunsemetinib expire in 2034. We currently do not have any patents issued directed to ATI-2231, but any claims that may issue would expire in 2040. Our issued U.S. patent covering ATI-1777 expires in 2038. Our issued U.S. patent directed to ATI-2138 expires in 2039. 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 or trademark 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 develop additional proprietary technologies that are not 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, other health care professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and for applicable manufacturers to

report annually to CMS information regarding ownership and investment interests held by physicians and their immediate family members; 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 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;
- requirements under the federal Open Payments program and its implementing regulations;
- a requirement to annually report drug samples that manufacturers and distributors provide to physicians; and
- the Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

There have been executive branch, 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 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 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 June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the Affordable Care Act is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. Thus, the Affordable Care Act will remain in effect in its current form. Prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the Affordable Care Act marketplace. The executive order also instructed 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 possible that the Affordable Care Act will be subject to judicial or Congressional challenges in the future. It is unclear how such challenges 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 and the Infrastructure Investment and Jobs Act, will stay in effect through 2031 with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 unless additional Congressional action is taken. Under current legislation the actual reduction in Medicare payments will vary from 1% in 2022 to up to 3% in the final fiscal year of this sequester. 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 concurrently released a final rule and guidance in September 2020 providing pathways 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 until January 1, 2023. 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. As a result of litigation challenging the Most Favored Nation model, on December 27, 2021, CMS published a final rule that rescinded the Most Favored Nation model interim final rule. In July 2021, the Biden administration released an executive order, "Promoting Competition in the American Economy," with multiple provisions aimed at prescription drugs. In response to Biden's executive order, on September 9, 2021, HHS released a Comprehensive Plan for Addressing High Drug Prices that outlines principles for drug pricing reform and sets out a variety of potential legislative policies that Congress could pursue as well as potential administrative actions HHS can take to advance these principles. No legislation or administrative actions have been finalized to implement these principles. It is unclear whether these or similar policy initiatives will be implemented in the future. 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, U.S. Customs regulations, the International Traffic in Arms Regulations, and economic embargo and trade sanction programs administered by the U.S. 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, and business development expertise of Dr. Neal Walker, our Chief Executive Officer, Frank Ruffo, our Chief Financial Officer, Dr. Joseph Monahan, our Chief Scientific Officer, and James Loerop, our Chief Business Officer, as well as the other members of our scientific and clinical teams. Although we have entered into employment agreements with our executive officers, each of them may currently terminate their employment with us 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 and/or results of any preclinical studies and 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 us and other pharmaceutical companies following periods of volatility in the market prices of these companies' stock. 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. Such 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.

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, 2021, we had federal and state net operating loss carryforwards, or NOLs, of $448.4 million and $404.9 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, 2021, we also had federal research and development tax credit carryforwards of $11.4 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 December 31, 2021. 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 December 31, 2021. 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, supply chain attacks, ransomware attacks, 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. For example, proposals have been made in Congress (which have not yet been enacted) that would make a number of changes to the federal income tax law applicable to corporations. 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 now that we no longer qualify as 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 sub-sublease 8,115 square feet of this space to a third party. The sub-sublease term runs concurrently with our sublease agreement.

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 alleged 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, and find that the materials minimized the risks or overstated the efficacy of the product. The complaint sought 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. Following briefing and oral argument on February 25, 2021, the motion was granted in part and denied in part on March 29, 2021, and the issues in dispute significantly narrowed. The defendants filed an answer to the remaining aspects of the consolidated amended complaint on April 19, 2021.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Securities Action. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to the putative class and scheduled the final approval settlement hearing for

November 30, 2021. Notice was subsequently given to the putative class. The court granted final approval of the settlement on December 9, 2021. Our financial obligation was within the limits of our insurance coverage.

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 alleged 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 sought, 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. On May 18, 2021, the court extended the stay – subject to certain conditions – until the resolution of a motion for summary judgment in the Consolidated Securities Action, which defendants in that action intended to file had the parties to the Consolidated Securities Action not reached an agreement to settle.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Derivative Action. The agreed terms require us to implement certain policies and for attorneys' fees to be paid to plaintiff's counsel, which were within the limits of our insurance coverage. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to our stockholders and scheduled the final approval settlement hearing for November 30, 2021. Notice was subsequently given to our stockholders. The court granted final approval of the settlement on December 9, 2021.

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, 2022, we had 61,275,033 shares of common stock outstanding held by 61 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

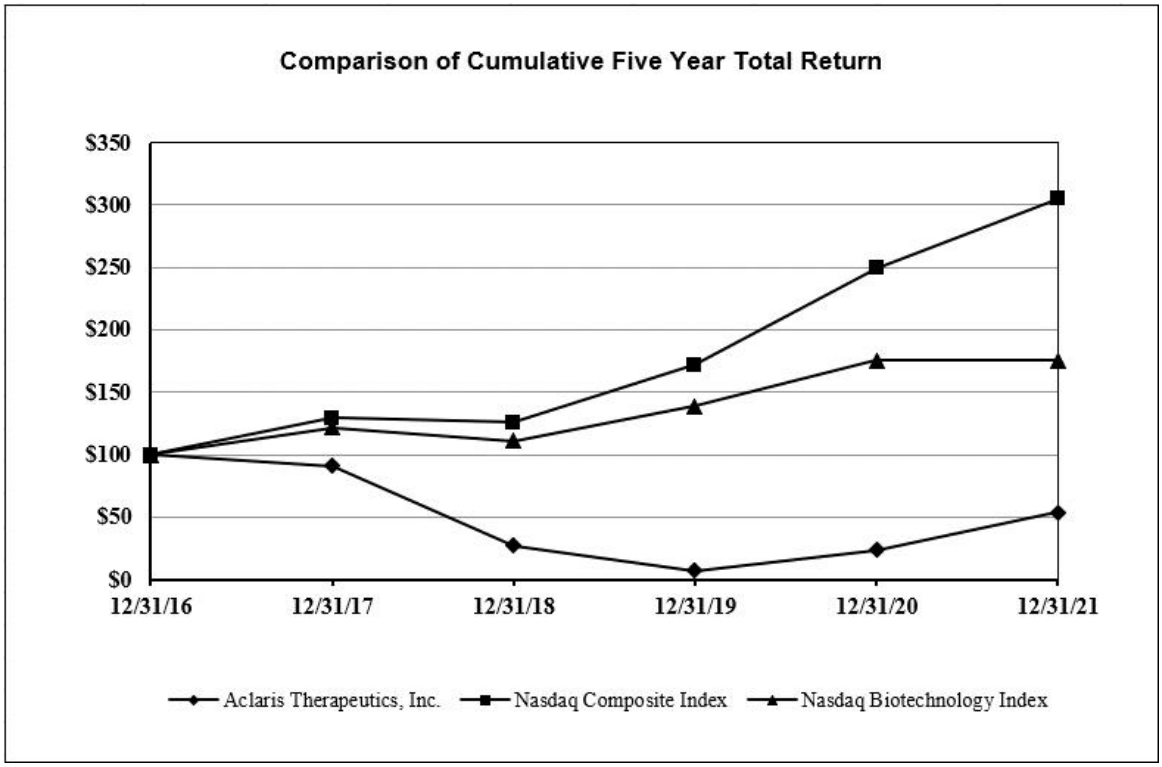
None.

Stock Performance Graph

The graph below compares the cumulative total stockholder return for the period December 31, 2016 through December 31, 2021 for (i) our common stock, (ii) the Nasdaq Biotechnology Index and (iii) the Nasdaq Composite Index. The graph assumes an investment of $100 on December 31, 2016 in each of our common stock, the Nasdaq Biotechnology Index and the Nasdaq Composite Index and the reinvestment of dividends, if any, although we have never declared or paid any dividends on our common stock. The stock price performance shown on the graph below is based on historical data and is not indicative of future stock price performance.

The graph and table below shall not be deemed "soliciting material" or to be "filed" with the SEC for purposes of Section 18 of the Exchange Act or otherwise subject to the liabilities under that Section, and shall not be deemed to be

incorporated by reference into any of our filings under the Securities Act or the Exchange Act.



	12/31/16	12/31/17	12/31/18	12/31/19	12/31/20	12/31/21
Aclaris Therapeutics, Inc.	$ 100.00	$ 90.86	$ 27.23	$ 6.96	$ 23.84	$ 53.57
Nasdaq Composite Index	$ 100.00	$ 129.64	$ 125.96	$ 172.18	$ 249.51	$ 304.85
Nasdaq Biotechnology Index	$ 100.00	$ 121.63	$ 110.85	$ 138.69	$ 175.33	$ 175.37

Item 6. [Reserved]

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.

Clinical Programs

Zunsemetinib, an Investigational Oral MK2 Inhibitor

We submitted an Investigational New Drug Application, or IND, in April 2019 for zunsemetinib, 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, IL17 and other essential pathogenic signals in chronic immuno-inflammatory diseases, as well as in oncology. As an oral drug candidate, we are developing zunsemetinib as a potential alternative to injectable anti-TNF/IL1/IL6 biologics and JAK inhibitors for treating certain immuno-inflammatory diseases. Zunsemetinib has been adopted as the nonproprietary name for ATI-450.

We initiated a Phase 1 single (at 10 mg, 30 mg, 50 mg and 100 mg doses) and multiple ascending (at 10 mg, 30 mg and 50 mg doses) dose clinical trial evaluating zunsemetinib in 77 healthy subjects in August 2019 (ATI-450-PKPD-101). Final data from this trial demonstrated that zunsemetinib resulted in marked inhibition of TNFα, IL1β, IL8 and IL6. We also observed that zunsemetinib 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. Zunsemetinib was generally well-tolerated at all doses tested in the trial. The most common adverse events (reported by 2 or more subjects who received zunsemetinib) were dizziness, headache, upper respiratory tract infection, constipation, abdominal pain and nausea.

Zunsemetinib was also evaluated at 80 mg and 120 mg doses twice daily in a second Phase 1 clinical trial in healthy subjects (ATI-450-PKPD-102). Final 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 zunsemetinib relative to doses tested in the first Phase 1 trial. 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 zunsemetinib) were headache, dizziness, nausea, parasthesia and, in the post-dosing follow-up period of the trial, dry skin. These adverse events were all mild in severity.

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 zunsemetinib in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-201). In the trial, which consisted of a 12-week treatment period and a 4-week follow-up period, 19 subjects were randomized in a 3:1 ratio and received either zunsemetinib at 50 mg twice daily or placebo, in combination with methotrexate, for 12 weeks.

The final per-protocol analysis, which consisted of the 17 subjects who completed the treatment period (15 in the treatment arm and two in the placebo arm), showed that zunsemetinib 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. Zunsemetinib 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, and ventricular extrasystoles, all of which were determined to be unrelated to treatment except for one UTI. Two subjects withdrew from the trial during the treatment period, one in the treatment arm and one in the placebo arm. The subject in the treatment arm withdrew due to an elevated creatine phosphokinase, or CPK, level, which was determined by the site investigator to be treatment-related; this subject also had palpitations and ventricular extrasystoles, which were unrelated to the trial medication. The subject in the placebo arm withdrew as a result of prohibited medication needed to treat muscle strain. There was also one non-treatment-related serious adverse event (COVID-19) reported in the 4-week follow-up period of the trial in a subject who was no longer receiving treatment; the subject withdrew during the 4-week follow-up period of the trial.

A final analysis, which consisted of the 17 subjects, 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 treatment 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.

In December 2021, we initiated study activities in a Phase 2b randomized, multicenter, double-blind, parallel group, placebo-controlled, dose ranging trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of multiple doses (20 mg and 50 mg twice daily) of zunsemetinib in combination with methotrexate in subjects with moderate to severe rheumatoid arthritis (ATI-450-RA-202). This trial will consist of a 12-week treatment period and a 30-day follow-up period, and currently seeks to enroll approximately 195 subjects in the United States and in multiple countries in Europe. The primary endpoint is the proportion of subjects achieving ACR20 at week 12. We anticipate increasing the size of the patient population to approximately 240 subjects and expect topline data in 2023.

Moderate to Severe Hidradenitis Suppurativa

In December 2021, we initiated study activities in a Phase 2a, randomized, multicenter, double-blind, placebo-controlled trial to investigate the efficacy, safety, tolerability, pharmacokinetics and pharmacodynamics of zunsemetinib (50 mg twice daily) in subjects with moderate to severe hidradenitis suppurativa (ATI-450-HS-201). This trial will consist of a 12-week treatment period and a 30-day follow-up period, and will seek to enroll approximately 70 subjects in the United States. The primary endpoint is the change in inflammatory nodule and abscess count at week 12. We expect topline data in the first half of 2023.

Moderate to Severe Psoriatic Arthritis

We plan to progress zunsemetinib (50 mg twice daily) into a Phase 2a trial in subjects with moderate to severe psoriatic arthritis in the first half of 2022, with topline data expected in the first half of 2023 (ATI-450-PsA-201).

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). In the trial, which consisted of a 4-week treatment period and a 2-week follow-up period during which no treatment was given, 50 subjects with moderate to severe atopic dermatitis were randomized in a 1:1 ratio into one of two arms: ATI-1777 topical solution 2.0% w/w or vehicle applied twice daily. In June 2021, we announced that the trial achieved its primary endpoint, which was the percent change from baseline in the modified Eczema Area and Severity Index, or mEASI, score at week 4, with a high degree of statistical significance ($p<0.001$) (one-sided p-value), which corresponded to a 74.4% reduction in mEASI score from baseline at week 4 in subjects applying ATI-1777 compared to a 41.4% reduction in subjects applying vehicle. The final data was based on the full analysis set, or FAS, which was comprised of 48 subjects randomized and documented to have received at least one dose of trial medication. Positive trends in favor of ATI-1777 were observed in key secondary efficacy endpoints, such as improvement in itch, percent of mEASI-50 responders, investigator's global assessment responder analysis, and reduction

in body surface area impacted by disease. In addition, the FAS analysis also showed positive trends in favor of ATI-1777 in percent of mEASI-75 responders (65.2% for ATI-1777 compared to 24.0% for vehicle) and mEASI-90 responders (30.4% for ATI-1777 compared to 20.0% for vehicle). These secondary efficacy endpoints were not powered for statistical significance. Based on an analysis of pharmacokinetic plasma samples in the ATI-1777 arm at multiple timepoints, minimal systemic exposure was observed which supports a "soft" topical JAK inhibitor approach.

ATI-1777 was generally well tolerated. No serious adverse events were reported. The most common adverse events (reported in at least 2 subjects in the trial) were increased blood CPK levels and headache in subjects in the ATI-1777 arm and urinary tract infection (one in each of the ATI-1777 and the vehicle arm); none of these adverse events in the ATI-1777 arm were determined by the clinical trial investigators to be related to ATI-1777. One treatment-related adverse event, application site pruritus, was reported in one subject in the ATI-1777 arm.

Based on the results observed in the Phase 2a trial, we intend to progress ATI-1777 into a Phase 2b trial in moderate to severe atopic dermatitis in the first half of 2022. In this trial, we plan to explore multiple concentrations of twice daily treatment with ATI-1777 and a single concentration of once daily treatment with ATI-1777, in patients 12 years and older. We expect topline data in the first half of 2023.

ATI-2138, an Investigational Oral ITJ Inhibitor

We are developing ATI-2138, an investigational oral ITK/TXK/JAK3, or ITJ, inhibitor compound, as a potential treatment for T cell-mediated autoimmune diseases. The ITJ compound interrupts T cell signaling through the combined inhibition of ITK/TXK/JAK3 pathways in lymphocytes. We submitted an IND for ATI-2138 for the treatment of psoriasis in October 2021, which was allowed by the FDA in November 2021.

In December 2021, we initiated a Phase 1 randomized, observer-blind, placebo-controlled, single ascending dose trial to investigate the safety, tolerability, pharmacokinetics and pharmacodynamics of ATI-2138 in healthy subjects (ATI-2138-PKPD-101). We expect topline data in 2022.

If the Phase 1 SAD trial is successful, we currently plan to initiate a two-week Phase 1 multiple ascending dose trial of ATI-2138 in subjects with psoriasis in 2022, with topline data expected in the first half of 2023. We are also currently exploring alternative indications to the planned indication that are relevant to the mechanism of action which may impact the trial design and require the submission of additional INDs to different reviewing divisions of the FDA.

Preclinical Programs

ATI-2231, an Investigational Oral MK2 Inhibitor

We are exploring the use of ATI-2231, an investigational oral MK2 inhibitor compound designed to have a long half-life, as a potential treatment for pancreatic cancer and metastatic breast cancer as well as in preventing bone loss in patients with metastatic breast cancer. IND-enabling studies are currently underway. We expect to submit an IND for ATI-2231 by the end of 2022. If allowed, we expect to progress ATI-2231 into the clinic in 2023. We are currently evaluating the clinical development program for this asset, which may include a collaboration with a third party.

Discovery Programs

We are developing oral gut-biased JAK inhibitors with limited systemic exposure as potential treatments for inflammatory bowel disease. In addition, we are engaged in research to identify brain penetrant kinase inhibitor candidates as potential treatments for neurodegenerative diseases.

Financial Overview

Since our inception, we have incurred significant net losses. Our net loss was $90.9 million for the year ended December 31, 2021 and $51.0 million for the year ended December 31, 2020. As of December 31, 2021, we had an accumulated deficit of $595.4 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. We also expect to add additional personnel to support our operational plans and strategic direction. 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.

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, staggered work schedules for lab personnel 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.

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 zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and other immuno-inflammatory diseases and ATI-1777 as a potential treatment for moderate to severe atopic dermatitis, and the supply of active pharmaceutical ingredients and drug product for our clinical trials. 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 spread of the disease, the introduction of new variants, the duration of the pandemic, travel restrictions, quarantines, stay-at-home orders, social distancing requirements, business closures, staffing shortages, 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.

Under the Confluence Agreement, we 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 closing consideration of $35.2 million. 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.

Components of Our Results of Operations

Revenue

Contract Research

We earn revenue from the provision of laboratory services. 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.

Other Revenue

Other revenue primarily consists of royalties earned on net sales of RHOFADE pursuant to the asset purchase agreement with EPI Health described above.

Cost of Revenue

Cost of revenue consists of the costs incurred in connection with the provision of contract research services. 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; and
- laboratory materials and supplies used to support our research activities.

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 zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and other immuno-inflammatory diseases, ATI-1777 as a potential treatment for moderate to severe atopic dermatitis and ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases, 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, clinical trial 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 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. 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 and travel expenses.

Revaluation of Contingent Consideration

Revaluation of contingent consideration consists of changes in the fair value of our contingent consideration liability between reporting dates.

Other Expense, Net

Other expense, net primarily consists of interest earned on our cash, cash equivalents and marketable securities, interest expense related to debt obligations, and gains and losses on transactions denominated in foreign currencies.

Critical Accounting 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.

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. 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. The fair value of an intangible asset is dependent on significant unobservable inputs including the estimated future cash flows of the asset.

There were no impairment losses recorded during the years ended December 31, 2021 and 2020.

Contingent Consideration

We initially recorded a contingent consideration liability at fair value on the date of acquisition related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of development, regulatory and commercial milestones, as well as estimated future sales levels and the discount rates applied to calculate the present value of the potential payments. Significant judgement was involved in determining the appropriateness of these assumptions. These assumptions are considered Level 3 inputs. Revaluation of our contingent consideration liability can result from changes to one or more of these assumptions. We evaluate the fair value estimate of our contingent consideration liability on a quarterly basis with changes, if any, recorded as income or expense in our consolidated statement of operations. Any such changes could have a material impact on our financial results.

The fair value of contingent consideration is estimated using a probability-weighted expected payment model for regulatory milestone payments and a Monte Carlo simulation model for commercial milestone and royalty payments and then applying a risk-adjusted discount rate to calculate the present value of the potential payments. Significant assumptions used in our estimates include the probability of achieving regulatory milestones and commencing

commercialization, which are based on an asset's current stage of development and a review of existing clinical data. Probability of success assumptions ranged between 10% and 40% at December 31, 2021 compared to between 4% and 15% at December 31, 2020. Additionally, estimated future sales levels and the risk-adjusted discount rate applied to the potential payments are also significant assumptions used in calculating the fair value. The discount rate ranged between 6.3% and 8.0% depending on the year of each potential payment.

During the year ended December 31, 2021, we updated assumptions for probability of success and estimated future sales levels as a result of the completion of a Phase 2a clinical trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis and as a result of the completion of a Phase 2a clinical trial of ATI-1777 in subjects with moderate to severe atopic dermatitis. We also included estimated future sales of zunsemetinib as a potential treatment for moderate to severe psoriatic arthritis and moderate to severe hidradenitis suppurativa, which are additional planned indications for zunsemetinib. These updates resulted in a charge of $24.3 million during the year ended December 31, 2021. During the year ended December 31, 2020, we updated assumptions for probability of success which resulted in a charge of $2.4 million.

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

For discussion on financial condition and results of operations pertaining to the year ended December 31, 2020 compared to the year ended December 31, 2019, see our Annual Report on Form 10-K for the year ended December 31, 2020, Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

Comparison of Years Ended December 31, 2021 and 2020

(In thousands)	Year Ended December 31, 2021	2020	Change
Revenues:			
Contract research	$ 5,830	$ 5,786	**$ 44**
Other revenue	931	696	**235**
Total revenue	6,761	6,482	**279**
Costs and expenses:			**—**
Cost of revenue	4,713	5,133	**(420)**
Research and development	43,813	29,338	**14,475**
General and administrative	23,619	20,530	**3,089**
Revaluation of contingent consideration	24,339	2,393	**21,946**
Total costs and expenses	96,484	57,394	**39,090**
Loss from operations	(89,723)	(50,912)	**(38,811)**
Other expense, net	(1,142)	(424)	**(718)**
Loss from continuing operations before income taxes	(90,865)	(51,336)	**(39,529)**
Income tax benefit	—	(182)	**182**
Loss from continuing operations	(90,865)	(51,154)	**(39,711)**
Income from discontinued operations	—	139	**(139)**
Net loss	$ (90,865)	$ (51,015)	**$ (39,850)**

Revenue

Contract research revenue was $5.8 million for each of the years ended December 31, 2021 and 2020, and was comprised of fees earned from the provision of laboratory services to our clients. Other revenue for the years ended December 31, 2021 and 2020 primarily consisted of $0.8 million and $0.7 million of royalties earned on net sales of RHOFADE, respectively.

Cost of Revenue

Cost of revenue was $4.7 million and $5.1 million for the years ended December 31, 2021 and 2020, respectively, and in each case related to providing laboratory services to our clients. The decrease in cost of revenue during the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily the result of the utilization of COVID-19 employee-retention tax credits.

Research and Development Expenses

The following table summarizes our research and development expenses by drug candidate or, for unallocated expenses, by type:

(In thousands)	Year Ended December 31, 2021	2020	Change
Zunsemetinib	$ 17,887	$ 8,268	$ 9,619
ATI-1777	2,439	3,993	(1,554)
ATI-2138	4,114	2,412	1,702
ATI-2231	2,949	—	2,949
Discovery	3,192	2,141	1,051
Other research and development	1,568	2,440	(872)
Personnel	7,798	7,165	633
Stock-based compensation	3,866	2,919	947
Total research and development expenses	$ 43,813	$ 29,338	$ 14,475

Zunsemetinib

The increase in expenses for zunsemetinib during the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily due to costs associated with drug candidate manufacturing and clinical development activities for a Phase 2b trial in subjects with moderate to severe rheumatoid arthritis and a Phase 2a trial in subjects with moderate to severe hidradenitis suppurativa, as well as other development activities including toxicology studies.

ATI-1777

The decrease in expenses for ATI-1777 during the year ended December 31, 2021 compared to the year ended December 31, 2020 was primarily due to a decrease in development costs, including toxicology studies, as well as a decrease in costs associated with a Phase 2a clinical trial in subjects with moderate to severe atopic dermatitis, which commenced in 2020 and concluded in 2021. These decreases were partially offset by startup activities associated with a Phase 2b clinical trial in subjects with moderate to severe atopic dermatitis.

ATI-2138

Expenses for ATI-2138 were higher during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to preclinical development activities and IND-enabling studies as we progressed towards our IND submission in October 2021. Clinical development expenses associated with a Phase 1 trial of ATI-2138 in healthy subjects which initiated in December 2021 also contributed to the increase.

ATI-2231

Expenses for ATI-2231 were higher during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to preclinical development activities and IND-enabling studies.

Discovery and other research and development

Expenses related to discovery increased during the year ended December 31, 2021 compared to the year ended December 31, 2020 due to continued investment in our discovery-stage programs.

Other research and development expenses, which primarily include expenses for our legacy dermatology assets and medical affairs activities, were lower during the year ended December 31, 2021 compared to the year ended December 31, 2020 due to a decrease in costs for our legacy dermatology assets following the decision to discontinue investment in those programs.

Personnel and stock-based compensation

Compensation related expenses increased during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to an increase in stock-based compensation expense associated with new equity awards granted in 2021 and personnel expenses as a result of higher average headcount, partially offset by lower payroll taxes resulting from the utilization of COVID-19 employee-retention tax credits.

General and Administrative Expenses

The following table summarizes our general and administrative expenses:

(In thousands)	Year Ended December 31, 2021	2020	Change
Personnel	$ 4,887	$ 5,671	$ (784)
Professional and legal fees	5,249	3,671	1,578
Facility and support services	1,984	1,743	241
Other general and administrative	2,286	2,103	183
Stock-based compensation	9,213	7,342	1,871
Total general and administrative expenses	$ 23,619	$ 20,530	$ 3,089

Personnel and stock-based compensation

Compensation related expenses increased during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to an increase in stock-based compensation expense associated with new equity awards granted in 2021, partially offset by a decrease in personnel expenses as a result of lower average headcount. Compensation related expenses during the year ended December 31, 2021 also included $1.7 million of expenses related to severance resulting from the retirement of our former Chief Legal Officer.

Professional and legal fees

Professional and legal fees, including accounting, investor relations and corporate communication costs, were higher during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily as a result of increased costs associated with Sarbanes-Oxley compliance and other professional fees.

Facility and support services and other general and administrative

Facility and support services, including general office expenses, information technology costs and other expenses, increased during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to an increase in information technology costs and infrastructure technology improvements.

Other general and administrative expenses increased during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to an increase in insurance premiums resulting from additional coverage in 2021 as compared to the prior year.

Revaluation of Contingent Consideration

The increase in revaluation of contingent consideration during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily resulted from updates to the probability of success and estimated future sales level assumptions as a result of the completion of a Phase 2a clinical trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis, as well as the completion of a Phase 2a clinical trial of ATI-1777 in subjects with moderate to severe atopic dermatitis. Additionally, the inclusion of estimated future sales of zunsemetinib as a potential treatment for moderate to severe psoriatic arthritis and moderate to severe hidradenitis suppurativa, which are additional planned indications for zunsemetinib, also contributed to the increase.

Other Expense, net

Other expense, net increased during the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily due to interest and fees associated with a payoff of the Loan and Security Agreement with Silicon Valley Bank, or SVB, as well as lower interest income.

Liquidity and Capital Resources

Overview

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 and incurring indebtedness in the form of loans from commercial lenders. We may engage in additional debt and equity financing transactions in order to raise funds. We may receive royalties and milestone payments from EPI Health in connection with the sale of RHOFADE. 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, 2021, we had cash, cash equivalents and marketable securities of $225.7 million. Cash in excess of immediate requirements is invested in accordance with our investment policy, primarily with a view towards liquidity and capital preservation.

We currently have no ongoing material financing commitments, such as lines of credit or guarantees, that are expected to affect our liquidity, other than our contingent obligations under the Confluence Agreement, which is summarized above under "Overview—Acquisition and License Agreements," and our lease obligations.

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 also incurred expenses of $0.4 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 $103.3 million.

June 2021 Public Offering

In June 2021, we closed a public offering in which we sold 8,098,592 shares of common stock at a price to the public of $17.75 per share, for aggregate gross proceeds of $143.8 million. We paid underwriting discounts and commissions of $8.6 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 $134.9 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 Capital Fund, LLC, or Lincoln Park, which 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 terminated the Purchase Agreement in January 2021 in connection with the public offering of common stock described above. We did not sell any additional shares prior to terminating the Purchase Agreement.

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 provided for $11.0 million in term loans, of which we borrowed the entire amount on March 30, 2020. In July 2021, we repaid in full the $11.0 million that was outstanding under the Loan and Security Agreement, together with all accrued and unpaid interest and fees as of the payoff date, for a total payment of $11.7 million.

Loan and Security Agreement with Oxford Finance LLC

In October 2018, we 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 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 as of the payoff date, for a total payment of $32.4 million.

Cash Flows

Cash and cash equivalents were $27.3 million as of December 31, 2021 compared to $22.1 million as of December 31, 2020. We also had $198.3 million in short- and long-term marketable securities as of December 31, 2021 compared to $32.1 million as of December 31, 2020.

The sources and uses of cash that contributed to the change in cash and cash equivalents were:

(In thousands)	Year Ended December 31, 2021	2020
Cash and cash equivalents beginning balance	$ 22,063	$ 35,937
Net cash used in operating activities	(52,134)	(38,633)
Net cash provided by (used in) investing activities	(167,632)	6,387
Net cash provided by financing activities	225,052	18,372
Cash and cash equivalents ending balance	$ 27,349	$ 22,063

Operating Activities

Cash flow related to operating activities was the result of:

(In thousands)	Year Ended December 31, 2021	2020
Net loss	$ (90,865)	$ (51,015)
Non-cash adjustments to reconcile net loss to net cash used in operating activities	40,074	14,742
Change in accounts payable and accrued expenses	4,125	(8,947)
Change in accounts receivable	149	4,898
Change in prepaid expenses and other assets	(5,617)	1,689
Net cash used in operating activities	$ (52,134)	$ (38,633)

Net cash used in operating activities increased for the year ended December 31, 2021 compared to the year ended December 31, 2020 primarily as a result of higher net losses after adjusting for revaluation of contingent consideration and other non-cash items, an increase in cash paid for prepaid expenses, and a reduction of cash collected from outstanding accounts receivable. The increase was partially offset by a decrease in cash paid to settle outstanding accounts payable balances.

The change in prepaid expenses and other assets was the result of higher prepaid research and development balances relative to the prior year period primarily associated with drug candidate manufacturing, clinical trial and preclinical development activities for zunsemetinib, ATI-1777 and ATI-2138. The change in accounts payable and accrued expenses was primarily driven by the timing of receipt and payment of invoices around year-end relative to the prior-year period. The change in accounts receivable was primarily the result of cash received during the year ended December 31, 2020 from Allergan Sales, LLC related to sales of RHOFADE that occurred after the date we sold RHOFADE to EPI Health.

Investing Activities

Cash flow related to investing activities was the result of:

(In thousands)	Year Ended December 31, 2021	2020
Purchases of property and equipment	$ (308)	$ (453)
Purchases of marketable securities	(235,153)	(47,714)
Proceeds from sales and maturities of marketable securities	67,829	54,554
Net cash provided by (used in) investing activities	$ (167,632)	$ 6,387

The change in net cash used in investing activities for the year ended December 31, 2021 compared to net cash provided by investing activities for the year ended December 31, 2020 primarily resulted from purchases of marketable securities following our January 2021 and June 2021 public offerings.

Financing Activities

Cash flow related to financing activities was the result of:

(In thousands)	Year Ended December 31, 2021	2020
Proceeds from issuance of common stock in connection with public offerings, net of issuance costs	$ 238,200	$ 7,737
Proceeds from debt financing (including warrants), net of issuance costs	—	10,913
Repayment of debt	(11,483)	—
Restricted stock unit employee tax withholdings	(3,124)	—
Finance lease payments	—	(137)
Deferred issuance costs	—	(211)
Proceeds from exercise of employee stock options and the issuance of stock	1,459	70
Net cash provided by financing activities	$ 225,052	$ 18,372

Cash provided by financing activities increased for the year ended December 31, 2021 compared to December 31, 2020 primarily due to our January 2021 and June 2021 public offerings. The increase was partially offset by a decrease in proceeds from debt financing, an increase in debt repayments, and an increase in cash used for tax withholdings in connection with the vesting of restricted stock units.

Funding Requirements

We anticipate we will incur net losses in the near term as we continue the clinical development of zunsemetinib as a potential treatment for moderate to severe rheumatoid arthritis and other immuno-inflammatory diseases, ATI-1777 as a potential treatment for moderate to severe atopic dermatitis and ATI-2138 as a potential treatment for T cell-mediated autoimmune diseases, 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 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. We expect to add additional personnel to support our operational plans and strategic direction. 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 similar 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 that could increase our compliance costs.

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 zunsemetinib, ATI-1777 and ATI-2138, 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
- our ability to earn revenue as a result of licenses to, or partnerships or other arrangements with, third parties.

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

Leases

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 concurrently 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. Our aggregate remaining lease payment obligations for these two spaces was $3.8 million as of December 31, 2021.

Agreement and Plan of Merger – Confluence

In August 2017, we entered into the Confluence Agreement, pursuant to which we acquired Confluence. Under the Confluence Agreement, we 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.

R&D Obligations

We enter into contracts in the normal course of business with CROs, contract manufacturing organizations and other service providers 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.

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.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

Our cash equivalents and marketable securities consist of money market funds, asset-backed debt securities, commercial paper, corporate debt securities and U.S. government agency debt securities. 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 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, 2021.

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.

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Aclaris Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2021 and 2020, 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, 2021, including the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2021 and 2020, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2021 in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2021, based on criteria established in *Internal Control - Integrated Framework* (2013) issued by the COSO.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in Management's Report on Internal Control over Financial Reporting appearing under Item 9A. Our responsibility is to express opinions on the Company's consolidated financial statements and on the Company's internal control over financial reporting 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud, and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the consolidated financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

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 the Contingent Consideration Liability related to zunsemetinib

As described in Notes 2 and 4 to the consolidated financial statements, the Company's contingent consideration balance was $28.4 million as of December 31, 2021, of which a significant portion of the liability relates to zunsemetinib. Management initially recorded a contingent consideration liability at fair value on the date of acquisition related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of development, regulatory and commercial milestones, as well as estimated future projected sales levels and the discount rates applied to calculate the present value of the potential payments. Management evaluates fair value estimates of the contingent consideration liability on a quarterly basis using a probability-weighted expected payment model for regulatory milestone payments and a Monte Carlo simulation model for commercial milestone and royalty payments and then applying a risk-adjusted discount rate to calculate the present value of the potential payment. 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 achieving regulatory milestones and commencing commercialization, which are based upon an asset's current stage of development and review of existing clinical data.

The principal considerations for our determination that performing procedures relating to the fair value of the contingent consideration liability related to zunsemetinib is a critical audit matter are (i) the significant judgment by management, when developing the fair value estimate, which in turn led to (ii) a high degree of auditor judgment, subjectivity and effort in performing procedures and evaluating management's significant assumptions related to the probability of achieving regulatory milestones and commencing commercialization. In addition, 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 testing the effectiveness of controls relating to management's contingent consideration evaluation, including controls over the valuation of the Company's contingent consideration liability related to zunsemetinib. These procedures also included, among others, (i) testing management's process for developing the fair value of the contingent consideration liability, (ii) evaluating the appropriateness of the probability-weighted expected payment and Monte Carlo simulation valuation models, (iii) testing the completeness and accuracy of the underlying data used in the models, and (iv) evaluating the reasonableness of the significant assumptions used by management related to the probability of achieving regulatory milestones and commencing commercialization. Evaluating management's assumptions related to the probability of achieving regulatory milestones and commencing commercialization involved evaluating whether the assumptions were reasonable considering the agreements associated with the transaction as well as the consistency with industry information, the stage of product development and whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in the evaluation of the Company's probability-weighted expected payment and Monte Carlo simulation valuation models.

/s/ PricewaterhouseCoopers LLP
Philadelphia, Pennsylvania
February 24, 2022

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, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 27,349	$ 22,063
Short-term marketable securities	164,065	32,068
Accounts receivable, net	623	772
Prepaid expenses and other current assets	12,995	2,590
Total current assets	205,032	57,493
Marketable securities	34,242	—
Property and equipment, net	1,335	1,654
Intangible assets	7,048	7,123
Other assets	3,554	4,514
Total assets	$ 251,211	$ 70,784
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 9,985	$ 5,254
Accrued expenses	10,051	5,906
Current portion of lease liabilities	693	603
Discontinued operations - current liabilities	2,202	3,111
Total current liabilities	22,931	14,874
Other liabilities	2,172	3,179
Long-term debt, net	—	10,653
Contingent consideration	28,400	4,061
Deferred tax liability	367	367
Total liabilities	53,870	33,134
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, 2021 and December 31, 2020	—	—
Common stock, $0.00001 par value; 100,000,000 shares authorized at December 31, 2021 and December 31, 2020; 61,228,446 and 45,109,314 shares issued and outstanding at December 31, 2021 and December 31, 2020, respectively	1	—
Additional paid-in capital	792,971	542,286
Accumulated other comprehensive loss	(224)	(94)
Accumulated deficit	(595,407)	(504,542)
Total stockholders' equity	197,341	37,650
Total liabilities and stockholders' equity	$ 251,211	$ 70,784

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,		
	2021	2020	2019
Revenues:			
Contract research	$ 5,830	$ 5,786	$ 4,227
Other revenue	931	696	—
Total revenue	6,761	6,482	4,227
Costs and expenses:			
Cost of revenue	4,713	5,133	4,055
Research and development	43,813	29,338	64,165
General and administrative	23,619	20,530	27,827
Revaluation of contingent consideration	24,339	2,393	734
Goodwill impairment	—	—	18,504
Total costs and expenses	96,484	57,394	115,285
Loss from operations	(89,723)	(50,912)	(111,058)
Other expense, net	(1,142)	(424)	(2,484)
Loss from continuing operations before income taxes	(90,865)	(51,336)	(113,542)
Income tax benefit	—	(182)	—
Loss from continuing operations	(90,865)	(51,154)	(113,542)
Income (loss) from discontinued operations, net of tax	—	139	(47,812)
Net loss	$ (90,865)	$ (51,015)	$ (161,354)
Net loss per share, basic and diluted	$ (1.60)	$ (1.20)	$ (3.90)
Weighted average common shares outstanding, basic and diluted	56,730,583	42,539,293	41,323,921
Other comprehensive income (loss):			
Unrealized gain (loss) on marketable securities, net of tax of $0	$ (229)	$ (2)	$ 28
Foreign currency translation adjustment	99	(26)	(25)
Total other comprehensive income (loss)	(130)	(28)	3
Comprehensive loss	$ (90,995)	$ (51,043)	$ (161,351)

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, 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
Issuance of common stock in connection with 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
Unrealized loss on marketable securities	—	—	378	(2)	—	376
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
Issuance of common stock in connection with exercise of stock options and warrants and vesting of restricted stock units	1,714,269	—	(1,574)	—	—	(1,574)
Issuance of common stock in connection with public offering, net of offering costs of $15,910	14,404,863	1	238,199	—	—	238,200
Unrealized loss on marketable securities	—	—	—	(229)	—	(229)
Foreign currency translation adjustment	—	—	—	99	—	99
Stock-based compensation expense	—	—	14,060	—	—	14,060
Net loss	—	—	—	—	(90,865)	(90,865)
Balance at December 31, 2021	61,228,446	$ 1	$ 792,971	$ (224)	$ (595,407)	$ 197,341

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,		
	2021	**2020**	**2019**
Cash flows from operating activities:			
Net loss	$ (90,865)	$ (51,015)	$ (161,354)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization	923	1,324	6,409
Stock-based compensation expense	14,060	11,207	16,177
Revaluation of contingent consideration	24,339	2,393	734
Goodwill impairment charge	—	—	18,504
Intangible asset impairment charge	—	—	27,638
Gain on sale of RHOFADE	—	—	(1,850)
Loss on extinguishment of debt	752	—	—
Deferred taxes	—	(182)	—
Changes in operating assets and liabilities:			
Accounts receivable	149	4,898	(809)
Prepaid expenses and other assets	(5,617)	1,689	3,233
Accounts payable	3,655	(5,219)	(3,160)
Accrued expenses	470	(3,728)	(1,967)
Net cash used in operating activities	(52,134)	(38,633)	(96,445)
Cash flows from investing activities:			
Purchases of property and equipment	(308)	(453)	(1,613)
Disposition of RHOFADE	—	—	34,186
Purchases of marketable securities	(235,153)	(47,714)	(137,385)
Proceeds from sales and maturities of marketable securities	67,829	54,554	210,491
Net cash provided by (used in) investing activities	(167,632)	6,387	105,679
Cash flows from financing activities:			
Proceeds from issuance of common stock in connection with public offerings, net of issuance costs	238,200	—	—
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	—
Repayment of debt	(11,483)	—	(30,000)
Restricted stock unit employee tax withholdings	(3,124)	—	—
Finance lease payments	—	(137)	(523)
Deferred issuance costs	—	(211)	—
Proceeds from exercise of employee stock options and the issuance of stock	1,459	70	207
Net cash provided by (used in) financing activities	225,052	18,372	(30,316)
Net increase (decrease) in cash, cash equivalents and restricted cash	5,286	(13,874)	(21,082)
Cash, cash equivalents and restricted cash at beginning of period	22,063	35,937	57,019
Cash, cash equivalents and restricted cash at end of period	$ 27,349	$ 22,063	$ 35,937
Supplemental disclosure of non-cash investing and financing activities:			
Additions to property and equipment included in accounts payable	$ 143	$ —	$ 124
Fair value of warrants issued in connection with debt financing	$ —	$ 378	$ —
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 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 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, 2021, the Company had cash, cash equivalents and marketable securities of $225.7 million and an accumulated deficit of $595.4 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 zunsemetinib (ATI-450), ATI-1777 and ATI-2138, to develop its preclinical compounds, and to support its discovery efforts.

Additional funds may not be available on a timely basis, on commercially acceptable terms, or at all, and such funds, if raised, may not be sufficient to enable the Company to continue to implement its long-term business strategy. 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, ATIL and Confluence. All 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, 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.

Contract Research

The Company earns contract research revenue from the provision of laboratory services. 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.

Cash Equivalents

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.

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 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. 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. 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 years ended December 31, 2021, 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 performed during the fourth quarter or when indicators of an impairment were present. The Company considered each of its operating segments, therapeutics and contract research, to be a reporting unit since that is the lowest level for which discrete financial information was available. The impairment test performed by the Company was a qualitative assessment based upon the then current facts and circumstances related to operations of the reporting unit. If the qualitative assessment indicated an impairment was 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 equal to the full balance of goodwill 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 at fair value on the date of acquisition related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of development, regulatory and commercial milestones, as well as estimated future sales levels

and the discount rates applied to calculate the present value of the potential payments. Significant judgement was involved in determining the appropriateness of these assumptions. These assumptions are considered Level 3 inputs. Revaluation of the contingent consideration liability can result from changes to one or more of these assumptions. The Company evaluates the fair value estimate of the contingent consideration liability on a quarterly basis with changes, if any, recorded as income or expense in the consolidated statement of operations.

The fair value of contingent consideration is estimated using a probability-weighted expected payment model for regulatory milestone payments and a Monte Carlo simulation model for commercial milestone and royalty payments and then applying a risk-adjusted discount rate to calculate the present value of the potential payments. Significant assumptions used in the Company's estimates include the probability of achieving regulatory milestones and commencing commercialization, which are based on an asset's current stage of development and a review of existing clinical data. Probability of success assumptions ranged between 10% and 40% at December 31, 2021. Additionally, estimated future sales levels and the risk-adjusted discount rate applied to the potential payments are also significant assumptions used in calculating the fair value. The discount rate ranged between 6.3% and 8.0% depending on the year of each potential payment.

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, 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.

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 primarily comprised of net loss 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. 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 Accounting Standards Update ("ASU") 2018-18, Collaborative Arrangements (Topic 808): Clarifying the Interaction Between Topic 808 and Topic 606, which, among other things, provides guidance on how to assess whether certain collaborative arrangement transactions should be accounted for under Topic 606. The 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.

3. RHOFADE Disposition

In October 2019, the Company entered into an asset purchase agreement with EPI Health, LLC ("EPI Health") pursuant to which the Company sold the worldwide rights to RHOFADE (oxymetazoline hydrochloride) cream, 1% ("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 closing consideration 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.

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, 2021			
(In thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 21,678	$ —	$ —	$ 21,678
Marketable securities	—	198,307	—	198,307
Total assets	$ 21,678	$ 198,307	$ —	$ 219,985
Liabilities:				
Contingent consideration	$ —	$ —	$ 28,400	$ 28,400
Total liabilities	$ —	$ —	$ 28,400	$ 28,400

	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:				
Contingent consideration	$ —	$ —	$ 4,061	$ 4,061
Total liabilities	$ —	$ —	$ 4,061	$ 4,061

As of December 31, 2021 and 2020, the Company's cash equivalents consisted of a money market fund, which was valued based upon Level 1 inputs. The Company's 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, 2021 and 2020 consisted of commercial paper and asset-backed and U.S. government agency debt securities, which were valued based upon Level 2 inputs. The Company's marketable securities as of December 31, 2021 also included corporate debt securities and foreign government agency 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, 2021 and 2020, there were no transfers into or out of Level 3.

The increase in contingent consideration of $24.3 million during the year ended December 31, 2021 primarily resulted from updates to the Company's probability of achieving regulatory milestones and commencing commercialization and estimated future sales level assumptions as a result of the completion of a Phase 2a clinical trial of zunsemetinib in subjects with moderate to severe rheumatoid arthritis and the inclusion of estimated future sales of zunsemetinib for the potential treatment of moderate to severe psoriatic arthritis and moderate to severe hidradenitis suppurativa, which are additional planned indications for zunsemetinib, as well as a result of the completion of a Phase 2a clinical trial of ATI-1777 in subjects with moderate to severe atopic dermatitis.

As of December 31, 2021 and 2020, the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

(In thousands)	December 31, 2021 Amortized Cost	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities[1]	$ 40,993	$ 6	(50)	$ 40,949
Commercial paper	71,837	—	—	71,837
Asset-backed debt securities	36,166	—	(43)	36,123
Foreign government agency debt securities	4,073	—	(13)	4,060
U.S. government agency debt securities[2]	45,465	—	(127)	45,338
Total marketable securities	$ 198,534	$ 6	$ (233)	$ 198,307

[1] Included in Corporate debt securities is $9.2 million with maturity dates between one and five years.

[2] Included in US government agency debt securities is $25.0 million with maturity dates between one and five years.

(In thousands)	December 31, 2020 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

5. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	December 31, 2021	December 31, 2020
Computer equipment	$ 1,380	$ 1,197
Lab equipment	1,605	1,340
Furniture and fixtures	620	617
Leasehold improvements	1,123	1,123
Property and equipment, gross	4,728	4,277
Accumulated depreciation	(3,393)	(2,623)
Property and equipment, net	$ 1,335	$ 1,654

Depreciation expense was $0.8 million, $1.1 million and $1.5 million for the years ended December 31, 2021, 2020 and 2019, respectively.

6. Intangible Assets

Intangible assets consisted of the following:

(In thousands, except years)	Remaining Life (years)	Gross Cost December 31, 2021	Gross Cost December 31, 2020	Accumulated Amortization December 31, 2021	Accumulated Amortization December 31, 2020
Other intangible assets	5.6	$ 751	$ 751	$ 332	$ 257
In-process research and development	n/a	6,629	6,629	—	—
Total intangible assets		$ 7,380	$ 7,380	$ 332	$ 257

Amortization expense was $75 thousand for each of the years ended December 31, 2021, 2020 and 2019.

As of December 31, 2021, estimated future amortization expense was as follows:

(In thousands)	Year Ending December 31,
2022	$ 75
2023	75
2024	75
2025	75
2026	75
Thereafter	44
Total	$ 419

7. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	December 31, 2021	December 31, 2020
Employee compensation expenses	$ 4,389	$ 3,971
Research and development expenses	1,278	761
Litigation settlements (see Note 20)	2,650	—
Other	1,734	1,174
Total accrued expenses	$ 10,051	$ 5,906

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 provided for $11.0 million in term loans, of which the Company borrowed the entire amount on March 30, 2020. 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.

In July 2021, the Company repaid in full the $11.0 million that was outstanding under the Loan and Security Agreement, together with all accrued and unpaid interest and fees as of the payoff date, for a total payment of $11.7 million. Following this repayment, all of the Company's obligations under the Loan and Security Agreement are deemed to be terminated, except as set forth in the agreement.

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 as of the payoff date, for a total payment of $32.4 million.

9. Stockholders' Equity

Preferred Stock

As of December 31, 2021 and 2020, 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, 2021 and 2020.

Common Stock

As of December 31, 2021 and 2020, 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. There were 61,228,446 and 45,109,314 shares of common stock issued and outstanding as of December 31, 2021 and 2020, respectively.

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, 2021.

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 an equity purchase agreement (the "Purchase Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park") which provided that, upon the terms and subject to the conditions and limitations set forth therein, the Company could 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 in connection with the public offering of common stock described below. The Company did not sell any additional shares prior to terminating the Purchase Agreement.

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 $0.4 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 $103.3 million.

June 2021 Public Offering

In June 2021, the Company closed a public offering in which it sold 8,098,592 shares of common stock at a price to the public of $17.75 per share, for aggregate gross proceeds of $143.8 million. The Company paid underwriting discounts and commissions of $8.6 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 $134.9 million.

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 in October 2015. 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, 2021, 2,708,469 shares remained available for grant under the 2015 Plan. As of January 1, 2022, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 2,449,137 shares. The Company had 2,897,705 stock options and 1,489,633 RSUs outstanding as of December 31, 2021 under the 2015 Plan.

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 410,600 stock options and 7,313 RSUs outstanding as of December 31, 2021 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 stock options to purchase a total of 1,140,524 shares under the 2012 Plan, of which 484,145 and 549,561 were outstanding as of December 31, 2021 and 2020, respectively. Stock options granted under the 2012 Plan 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, 2021, 2020 and 2019 were as follows:

	Year Ended December 31,		
	2021	2020	2019
Risk-free interest rate	0.92 %	0.87 %	2.27 %
Expected term (in years)	6.2	6.1	6.2
Expected volatility	76.60 %	85.19 %	99.36 %
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 forfeitures in the period when they occur.

Stock Options

The following table summarizes stock option activity for the years ended December 31, 2021, 2020 and 2019:

(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, 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
Granted	1,068,100	23.44		
Exercised	(115,548)	12.63		1,373
Forfeited and cancelled	(31,600)	23.26		
Outstanding as of December 31, 2021	3,792,450	$ 17.50	6.8	$ 13,710
Options vested and expected to vest as of December 31, 2021	3,792,450	$ 17.50	6.8	$ 13,710
Options exercisable as of December 31, 2021	2,200,718	$ 17.86	5.4	$ 7,756

The weighted average grant date fair value of stock options granted during the years ended December 31, 2021, 2020 and 2019 was $15.67, $0.93 and $4.63 per share, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2021, 2020 and 2019.

(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, 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	
Granted	664,948	23.33	
Vested	(1,340,042)	3.18	$ 31,492
Forfeited and cancelled	(72,117)	10.36	
Outstanding as of December 31, 2021	1,496,946	$ 12.75	

Stock-Based Compensation

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

	Year Ended December 31,		
(In thousands)	2021	2020	2019
Cost of revenue	$ 981	$ 946	$ 703
Research and development	3,866	2,919	5,091
General and administrative	9,213	7,342	10,288
Total stock-based compensation expense	$ 14,060	$ 11,207	$ 16,082

As of December 31, 2021, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $13.4 million and $13.8 million, respectively, which is expected to be recognized over weighted average periods of 3.0 years and 2.9 years, respectively.

11. Net Loss per Share

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

	Year Ended December 31,		
(In thousands, except for share and per share data)	2021	2020	2019
Numerator:			
Net loss	$ (90,865)	$ (51,015)	$ (161,354)
Denominator:			
Weighted average shares of common stock outstanding, basic and diluted	56,730,583	42,539,293	41,323,921
Net loss per share, basic and diluted	$ (1.60)	$ (1.20)	$ (3.90)

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 is the same. The following table presents potential shares of common stock excluded from the calculation of diluted net loss per share for the years ended December 31, 2021, 2020 and 2019. All share amounts presented in the table below represent the total number outstanding as of December 31 of each year.

	December 31,		
	2021	2020	2019
Options to purchase common stock	3,792,450	2,871,498	3,102,221
Restricted stock unit awards	1,496,946	2,244,157	3,592,915
Warrants	—	460,251	—
Total potential shares of common stock	5,289,396	5,575,906	6,695,136

12. Leases

The Company has operating leases for office space and laboratory facilities, and had finance leases for its laboratory equipment and vehicles. The components of lease expense were as follows:

(In thousands)	Year Ended December 31, 2021	2020	2019
Operating lease expense	$ 1,013	$ 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 for each of the years ended December 31, 2021, 2020 and 2019, which was recognized on a straight-line basis over the term of the lease.

Operating Leases

Agreements for Office and Laboratory 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 to a third party. The sub-sublease term runs concurrently 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, 2021	December 31, 2020
Operating Leases:		
Gross cost	$ 5,240	$ 5,240
Accumulated amortization	(1,803)	(1,111)
Other assets	$ 3,437	$ 4,129
Current portion of lease liabilities	$ 693	$ 603
Other liabilities	2,201	2,894
Total operating lease liabilities	$ 2,894	$ 3,497

Amortization expense related to operating lease right-of-use assets and accretion of operating lease liabilities totaled $1.0 million for each of the years ended December 31, 2021, 2020 and 2019.

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, for 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. 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.

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:	**2021**	**2020**	**2019**
Operating cash flows from operating leases	$ 924	$ 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	5.4	6.0	6.8
Weighted-Average Discount Rate:			
Operating leases	10.1 %	10.1 %	10.1 %

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

(In thousands) Year Ending December 31,	Operating Leases
2022	$ 949
2023	866
2024	343
2025	352
2026	361
Thereafter	941
Total undiscounted lease payments	3,812
Less: unrecognized interest	(918)
Total lease liability	$ 2,894

13. Income Taxes

During the years ended December 31, 2021, 2020 and 2019, the Company did not record an income tax benefit for net operating losses incurred in each year due to the uncertainty of realizing a benefit from those items.

Loss before income taxes is allocated as follows:

	Year Ended December 31,		
(In thousands)	2021	2020	2019
U.S. operations	$ (90,865)	$ (51,215)	$ (161,192)
Foreign operations	—	18	(162)
Loss before income taxes	$ (90,865)	$ (51,197)	$ (161,354)

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,		
	2021	2020	2019
Federal statutory income tax rate	(21.0)%	(21.0)%	(21.0)%
State taxes, net of federal benefit	(7.7)	(7.5)	(6.6)
Research and development tax credits	(3.0)	(2.6)	(1.5)
Excess equity compensation tax benefit net of officer limitation	(3.9)	1.4	0.4
Revaluation of contingent consideration	5.6	1.0	—
Permanent differences	—	0.2	2.6
Change in deferred tax asset valuation allowance	30.0	28.1	26.2
Effective income tax rate	— %	(0.4)%	0.1 %

Deferred tax liabilities, net consisted of the following:

	December 31,	
(In thousands)	2021	2020
Deferred tax assets:		
Net operating loss carryforwards	$ 123,583	$ 101,277
Capitalized start-up costs	6,334	6,509
Research and development tax credit carryforwards	11,502	8,732
Capitalized research and development expense	4,046	4,611
Stock-based compensation expense	17,728	14,526
Accrued compensation	825	745
Lease liabilities	721	888
Other	648	602
Total deferred tax assets	165,387	137,890
Deferred tax liabilities:		
Property and equipment	(171)	(209)
Intangible asset	(1,567)	(2,033)
Right-to-use assets	(852)	(1,026)
Other	(1,340)	(430)
Total deferred tax liabilities	(3,930)	(3,698)
Valuation allowance	(161,824)	(134,559)
Deferred tax liabilities, net	$ (367)	$ (367)

As of December 31, 2021, the Company had federal and state net operating loss ("NOL") carryforwards of $448.4 million and $404.9 million, respectively, which will begin to expire in 2032. As of December 31, 2021, the Company also had federal research and development tax credit carryforwards of $11.4 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 December 31, 2021. 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 December 31, 2021. 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, 2021 and 2020. 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, 2021, 2020 and 2019 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)	2021	2020	2019
Valuation allowance at beginning of year	$ (134,559)	$ (120,966)	$ (80,985)
Decreases recorded as benefit to income tax provision	—	—	—
Decreases recorded to opening balance sheet	—	58	—
Increases recorded to income tax provision	(27,265)	(13,651)	(39,981)
Valuation allowance as of end of year	$ (161,824)	$ (134,559)	$ (120,966)

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 2019 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, the Company entered into a master services agreement with a subsidiary of Mallinckrodt plc, pursuant to which Confluence provides laboratory services to a 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, 2021 and 2020, the Company invoiced Mallinckrodt for $24 thousand and $0.3 million, respectively, under the master services agreement. As of December 31, 2021 and 2020, the Company had $0 and $24 thousand 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 $0.8 million and $0.7 million during the years ended December 31, 2021 and 2020, 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 Sales, LLC ("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, $0 and $1.4 million during the years ended December 31, 2021, 2020 and 2019, 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"). Under the Confluence Agreement, the Company 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.

As of December 31, 2021 and December 31, 2020, the balance of the Company's contingent consideration liability was $28.4 million and $4.1 million, respectively (see Note 4).

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. 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. The Company terminated the license and collaboration with Rigel effective as of April 2021.

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 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 $0.3 million, $0.4 million and $0.7 million for the years ended December 31, 2021, 2020 and 2019, 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

Significant Accounting Policies

Revenue Recognition

Product Sales, net

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 group purchasing organizations 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 had a product returns policy for RHOFADE that provided 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 (hydrogen peroxide) topical solution, 40% (w/w) ("ESKATA"), as the Company had a no returns policy for ESKATA when it was commercialized.

Intangible Assets

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).

Financial Information

The components of income (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)	**2021**	**2020**	**2019**
Revenues:			
Product sales, net	$ —	$ 424	$ 13,896
Total revenue, net	—	424	13,896
Costs and expenses:			
Cost of revenue (excludes amortization)	—	—	4,522
Research and development	—	1	503
Sales and marketing	—	283	23,112
General and administrative	—	1	2,929
Intangible asset impairment	—	—	27,638
Amortization of definite-lived intangible	—	—	4,426
Total costs and expenses	—	285	63,130
Income (loss) from operations	—	139	(49,234)
Other income, net	—	—	1,422
Income (loss) from discontinued operations	$ —	$ 139	$ (47,812)
Net income (loss) from discontinued operations per share, basic and diluted	$ —	$ 0.00	$ (1.16)
Weighted average common shares outstanding, basic and diluted	56,730,583	42,539,293	41,323,921

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

	Year Ended December 31,		
(In thousands)	**2021**	**2020**	**2019**
ESKATA	$ —	$ —	$ 312
RHOFADE	—	424	13,584
Total product sales, net	$ —	$ 424	$ 13,896

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 liabilities reported as discontinued operations in the Company's consolidated balance sheet:

(In thousands)	December 31, 2021	December 31, 2020
Accounts payable	$ —	$ 1,175
Accrued expenses	2,202	1,936
Discontinued operations - current liabilities	$ 2,202	$ 3,111

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. 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, 2021, 2020 and 2019 are summarized in the tables below:

(In thousands) Year Ended December 31, 2021	Therapeutics	Contract Research	Corporate and Other	Total Company
Total revenue	$ 932	$ 13,447	$ (7,618)	$ 6,761
Cost of revenue	—	11,885	(7,172)	4,713
Research and development	44,259	—	(446)	43,813
General and administrative	—	3,047	20,572	23,619
Revaluation of contingent consideration	24,339	—	—	24,339
Loss from operations	$ (67,666)	$ (1,485)	$ (20,572)	$ (89,723)

(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	29,777	—	(439)	29,338
General and administrative	—	2,794	17,736	20,530
Revaluation of contingent consideration	2,393	—	—	2,393
Loss from operations	$ (31,474)	$ (1,703)	$ (17,735)	$ (50,912)
Income (loss) from discontinued operations	$ 140	$ —	$ (1)	$ 139

(In thousands) Year Ended December 31, 2019	Therapeutics	Contract Research	Corporate and Other	Total Company
Revenue, net	$ —	$ 16,824	$ (12,597)	$ 4,227
Cost of revenue	—	16,253	(12,198)	4,055
Research and development	64,564	—	(399)	64,165
Revaluation of contingent consideration	734	—	—	734
Goodwill impairment	18,504	—	—	18,504
General and administrative	620	2,738	24,469	27,827
Loss from operations	$ (84,422)	$ (2,167)	$ (24,469)	$ (111,058)
Loss from discontinued operations	$ (46,305)	$ —	$ (1,507)	$ (47,812)

Intersegment Revenue

Revenue for the contract research segment included $7.6 million, $7.5 million and $12.6 million for services performed on behalf of the therapeutics segment for the years ended December 31, 2021, 2020 and 2019, 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 alleged 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 sought 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. Following briefing and oral argument on February 25, 2021, the motion was granted in part and denied in part on March 29, 2021, and the issues in dispute significantly narrowed. The defendants filed an answer to the remaining aspects of the consolidated amended complaint on April 19, 2021.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Securities Action. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to the putative class and scheduled the final approval settlement hearing for November 30, 2021. Notice was subsequently given to the putative class. The court granted final approval of the settlement on December 9, 2021.

The Company had $2.65 million accrued as of December 31, 2021 for its financial obligation. The Company's financial obligation was within the limits of its insurance coverage and accordingly a receivable for an insurance recovery equal to the settlement amount was recorded. The insurance recovery receivable and the litigation settlement liability are recorded in prepaid expenses and other current assets and accrued expenses, respectively, in the consolidated balance sheet.

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 alleged 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 sought, 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' then-anticipated motion to dismiss the Consolidated Securities Action. On May 18, 2021, the court extended the stay – subject to certain conditions – until the resolution of a motion for summary judgment in the Consolidated Securities Action, which defendants in that action intended to file had the parties to the Consolidated Securities Action not reached an agreement to settle.

In June 2021, the defendants and the plaintiffs agreed to settle the Consolidated Derivative Action. The agreed terms require the Company to implement certain policies and for attorneys' fees to be paid to plaintiff's counsel. The parties signed and filed a settlement agreement in July 2021. On August 18, 2021, the court preliminarily approved the proposed settlement, directed that notice be given to the Company's stockholders and scheduled the final approval settlement hearing for November 30, 2021. Notice was subsequently given to the Company's stockholders. The court granted final approval of the settlement on December 9, 2021.

The Company's financial obligation under the settlement was $425 thousand which was within the limits of its insurance coverage.

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 sought unspecified compensatory and punitive damages. The Company filed a motion to dismiss the amended complaint on March 15, 2021. The Company's motion to dismiss was granted on July 9, 2021. The Court dismissed the majority of claims against the Company with prejudice. All remaining claims against the Company were dismissed without prejudice.

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, 2021, 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 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 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, 2021, 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.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-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 our internal control over financial reporting was effective as of December 31, 2021 to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with U.S. GAAP. Our independent registered public accounting firm, PricewaterhouseCoopers LLP, has issued an audit report with respect to our internal control over financial reporting, which appears in Part II, Item 8 of this Annual Report.

Changes in Internal Control over Financial Reporting

There were no changes 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, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Disclosure Controls and Procedures and Internal Control over Financial Reporting

In designing and evaluating the disclosure controls and procedures and internal control over financial reporting, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives. In addition, the design of disclosure controls and procedures and internal control over financial reporting must reflect the fact that there are resource constraints and that management is required to apply judgment in evaluating the benefits of possible controls and procedures relative to their costs.

Item 9B. Other Information

Not applicable.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

We will file a definitive Proxy Statement for our 2022 Annual Meeting of Stockholders, or the 2022 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 2022 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 2022 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 2022 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 2022 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 2022 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 2022 Proxy Statement under the caption “Ratification of Selection of Independent Registered Public Accounting Firm.”

PART IV

Item 15. Exhibits and Financial Statement Schedules

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

(1) Financial Statements

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

(2) Financial Statement Schedules

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

(3) *Exhibits*

See exhibits listed under part (b) below.

(b) Exhibits

Exhibit Number	Description of Document
2.1#	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 (incorporated by reference to Exhibit 4.2 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 25, 2021).
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+*	Sixth Amended and Restated Non-Employee Director Compensation Policy.
10.13+	Amended and Restated Employment Agreement, dated as of January 12, 2022, by and between the Registrant and Neal Walker (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 January 14, 2022).
10.14+	Amended and Restated Employment Agreement, dated as of January 12, 2022, by and between the Registrant and Frank Ruffo (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 January 14, 2022).
10.15+*	Employment Agreement, dated as of January 12, 2022, by and between the Registrant and Joseph Monahan.
10.16+*	Employment Agreement, dated as of January 31, 2022, by and between the Registrant and James Loerop.
10.17+*	Severance Agreement and General Release, dated as of November 1, 2021, by and between the Registrant and Kamil Ali-Jackson.
10.18+*	Severance Agreement and General Release, dated as of January 7, 2022, by and between the Registrant and David Gordon.
10.19	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).
10.20	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).
10.21	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).
10.22	Sales Agreement, dated May 20, 2021, by and among the Registrant, SVB Leerink LLC and Cantor Fitzgerald & Co. (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 May 20, 2021).
10.23+*	Seventh Amended and Restated Non-Employee Director Compensation Policy.
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)

* 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 24, 2022

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Neal Walker 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 24, 2022
/s/ Frank Ruffo Frank Ruffo	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 24, 2022
/s/ Christopher Molineaux Christopher Molineaux	Chairman of the Board of Directors	February 24, 2022
/s/ Anand Mehra, M.D. Anand Mehra, M.D.	Director	February 24, 2022
/s/ William Humphries William Humphries	Director	February 24, 2022
/s/ Andrew Powell Andrew Powell	Director	February 24, 2022
/s/ Andrew Schiff Andrew Schiff	Director	February 24, 2022
/s/ Bryan Reasons Bryan Reasons	Director	February 24, 2022
/s/ Maxine Gowen Maxine Gowen	Director	February 24, 2022
/s/ Vincent Milano Vincent Milano	Director	February 24, 2022

ACLARIS THERAPEUTICS, INC.

SIXTH 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 Sixth Amended & Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service effective as of November 10, 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
    d. Member of the Research and Development Committee: $6,000

3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):

    a. Chair of the Audit Committee: $12,500
    b. Chair of the Compensation Committee: $8,000
    c. Chair of the Nominating and Corporate Governance Committee: $4,500
    d. Chair of the Research and Development Committee: $8,000

4. Annual Chair 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 have 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 awards (the "***Initial Award***") with an aggregate grant date fair value (as calculated for financial reporting purposes) equal to the lesser of $320,000 and the grant date fair value of 17,500

stock options, 70% of which shall be granted as a stock option to purchase shares of the Company's Common Stock and 30% of which shall be granted as restricted stock units. 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 (as defined in the Plan) through such vesting dates.

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 awards (the "***Annual Award***") with an aggregate grant date fair value (as calculated for financial reporting purposes) equal to the lesser of $320,000 and the grant date fair value of 17,500 stock options, 70% of which shall be granted as a stock option to purchase shares of the Company's Common Stock and 30% of which shall be granted as restricted stock units; provided that in no event shall the aggregate grant date fair value of an Annual Award together with an Initial Award in a fiscal year exceed $320,000 for any Eligible Director. 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 dates.

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "***Employment Agreement***"), effective as of January 12, 2022 ("***Agreement Effective Date***"), is made by and between Aclaris Therapeutics, Inc., a corporation organized under the laws of the State of Delaware ("***Employer***") and Joseph Monahan ("***Executive***").

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

WHEREAS, Employer and Executive desire to formalize the terms and conditions of Executive's employment with Employer; and

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

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

SECTION 1. EMPLOYMENT

1.1 General. Employer hereby agrees to continue to employ Executive in the capacity of Chief Scientific Officer ("***CSO***"). Executive hereby accepts such continued employment upon the terms and subject to the conditions herein contained.

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

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

1.2.2 Time to Be Devoted to Employment. During Executive's Employment with Employer, Executive shall diligently devote his efforts, business time, attention and energies to the business of Employer and will not, while employed by Employer, undertake or engage in any other employment, occupation or business enterprise that would interfere with Executive's responsibilities and the performance of Executive's duties hereunder except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Executive may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties; and (iii) reasonable time devoted to service as a member of the board of directors of the entities listed on Exhibit A or as otherwise permitted pursuant to Section 1.3. This restriction shall not, however, preclude Executive (x) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (y) from employment or service in any capacity with Affiliates of Employer. As used in this Employment Agreement, "Affiliates" means an entity under common management or control with Employer.

1.3 Other Responsibilities. Notwithstanding Section 1.2.2 above, Executive will not engage in any other for-profit business, profession or occupation, including as a member of a board of directors of any third party, for compensation which would materially conflict or materially interfere with the rendition of services hereunder, without the prior written consent of the Board, which shall not be unreasonably withheld. Any uncertainty as to whether such a conflict exists will be raised by Executive for determination by the Board, acting reasonably. The Board acknowledges that Executive has ongoing participation in other private and public businesses that have been disclosed by Executive and are listed on Exhibit A and that such participation does not, in any way, conflict with his role at Employer. Except for the businesses listed on Exhibit A, which have already been approved, Executive agrees to disclose to the Board and receive prior written consent from the Board to participate as a director, with any competing company whether it is a private or public company. Executive further agrees to disclose any other director positions with any other company that may materially affect his ability to perform his duties and responsibilities under this Employment Agreement. Notwithstanding the above, nothing herein shall limit or preclude Executive from managing any passive investments made by Executive.

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

SECTION 2. COMPENSATION AND BENEFITS

2.1 Salary. Employer will pay to Executive an annual base salary of $350,000 payable subject to standard federal and state payroll withholding requirements in accordance with the regular payroll practices of Employer ("***Base Salary***"). The annual Base Salary may be increased (but not decreased) during the term of this Employment Agreement by the Board in its sole discretion.

2.2 Additional Compensation. In addition to the salary set forth in Section 2.1, Executive shall be entitled to receive a cash bonus in accordance with the terms of this Section 2.2. For each fiscal year of Employer, beginning January 1, during the Employment Term (as defined in Section 2.4 hereof), Executive shall be eligible to receive a cash bonus based on (i) the "***Annual Bonus Expectancy Amount***," which shall be an amount equal to 40% of Executive's Base Salary for the applicable fiscal year, and (ii) Executive's attainment of performance targets and other reasonable criteria established by the Board, to the extent possible, by the end of the first month of such fiscal year. Depending on the targets and criteria which are achieved or met, the amount of the cash bonus actually payable to Executive for each fiscal year will be an amount from zero to and including the Annual Bonus Expectancy Amount. Any cash bonus amount payable pursuant to this Section 2.2 shall be paid to Executive as soon as practicable, but in no event later than two and one-half (2 1/2) months, following the end of the fiscal year to which it relates. For the avoidance of doubt, Executive does not have to be employed by Employer on the date such bonus is approved or paid by Employer to receive such bonus.

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

2.3.1 Expenses. Employer will promptly reimburse Executive for expenses he reasonably incurs in connection with the performance of his duties (including business travel and entertainment expenses), in accordance with Employer's standard expense reimbursement policy, as the same may be modified by Employer from time to time; provided, however, that Executive has provided Employer with documentation of such expenses in accordance with the Employer's expense reimbursement policies and applicable tax requirements. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"): (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Employment Agreement will not be subject to liquidation or exchange for another benefit.

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

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

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

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

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

SECTION 3. TERMINATION OF EMPLOYMENT

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

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

3.1.2 Disability. In the event of Executive's Disability (as hereinafter defined), Employer will have the option to terminate Executive's employment by giving a notice of termination to Executive. The notice of termination shall specify the date of termination, which date shall not be earlier than thirty (30) calendar days after the notice of termination is given. For purposes of this Employment Agreement, "***Disability***" has the meaning set forth in Employer's long term disability plan.

3.1.3 Termination by Employer for Cause. Employer may, at its option, terminate Executive's employment for Cause (as hereinafter defined) by unilateral action of the Board of Directors upon giving a notice of termination to Executive. "***Cause***" shall mean (i) Executive's conviction of, or guilty plea to, a felony (other than traffic violations); (ii) any act(s) or omission(s) by Executive which constitutes gross negligence or a material breach of Executive's duty of loyalty; (iii) any material breach by Executive of Employer's personnel policies; (iv) refusal to follow or implement a clear and reasonable directive of Employer; (v) breach of fiduciary duty; or (vi) a material violation or breach by Executive of this Employment Agreement (other than an event described in the foregoing clauses) or any other agreement between the parties.

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

3.1.5 By Executive. Executive may, at any time, terminate Executive's employment for any reason whatsoever by giving a notice of termination to Employer. Executive's employment shall terminate on the earlier of (i) thirty (30) calendar days after the date of receipt by Employer of the notice of termination or (ii) such earlier date as the Employer and Executive shall agree.

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

period. In such event, Employer shall pay Executive all compensation in accordance with Section 3.2.3.

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

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

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

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

(iv) Executive's place of employment is changed to a location that is greater than fifty (50) miles from Executive's current place of employment which is contemplated to be in Wayne, Pennsylvania; or

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

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

3.2.1 Death; Disability; Termination by Employer Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated by Employer pursuant to Section 3.1.1 ("***Death***"), Section 3.1.2 ("***Disability***"), Section 3.1.4 ("***Without Cause by Employer***") or by Executive pursuant to Section 3.1.7 ("***Termination by Executive for Good Reason***") hereof, and Executive, or his estate, as the case may be, executes and does not revoke a separation agreement containing a release upon such termination, in a form provided by the Employer, of any and all claims against Employer and all related parties

with respect to all matters arising out of Executive's employment by Employer, or the termination thereof (the "***Release***") in accordance with Section 3.7, Executive, or his estate, as the case may be, shall be entitled to the following payments and benefits, which payments and benefits shall be paid in accordance with this Section 3.2.1 and Section 3.7:

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

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

(iii) So long as Executive is eligible, and so long as Executive remains eligible, for and upon his timely election of coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or, if applicable, state or local insurance laws ("***COBRA***"), Employer will continue to pay, directly to the healthcare provider when due, Employer's portion of the medical, vision and dental coverage premiums (and Executive will be responsible for Executive's portion) for a period of twelve (12) months after the effective date of Executive's termination (the "***COBRA Payment Period***"); provided that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for the remainder of the COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA Payment Period; and

(iv) In the event such termination of employment occurs on or within three (3) months prior to or within twelve (12) months following the effective date of a Change of Control (as defined herein), Executive shall be entitled to the <u>additional</u> following payments and benefits (for the avoidance of doubt, Executive shall also be entitled to the amounts set forth in Section 3.2.1(i)-(iii)):

(1) Employer shall pay to Executive a lump sum payment equal to the Annual Expectancy Bonus Amount (target bonus), less applicable deductions and withholdings, paid within thirty (30) days of the later of (a) the

effective date of the Change of Control or (b) Executive's termination, if such termination occurs on or after the effective date of a Change of Control; and

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

For purposes of this Employment Agreement, "***Change of Control***" means, in each case as approved by the Board and the requisite stockholders of Employer, (i) any consolidation or merger of Employer with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of Employer immediately prior to such consolidation, merger or reorganization, own, in the aggregate, less than 50% of the surviving entity's voting power and/or outstanding capital stock immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions (including any transaction which results from an option agreement or binding letter of intent with a third party) to which Employer or any of its stockholders is a party in which in excess of 50% of Employer's voting power and/or outstanding capital stock is transferred, or pursuant to which any person or group of affiliated persons obtains in excess of 50% of Employer's voting power and/or outstanding capital stock, excluding any consolidation or merger effected exclusively to change the domicile of Employer; or (ii) any sale, license or other disposition (including through a Board and stockholder approved division or spin-off transaction) of all or substantially all of the assets of Employer and/or any of its subsidiaries or any sale, exclusive license or other disposition of all or substantially all of Employer's intellectual property, as reasonably determined based upon the potential earning power of the assets or intellectual property; provided, however, that none of the following shall constitute a Change of Control: (A) transfers of capital stock by an existing stockholder as a result of death or otherwise for estate planning purposes or to such stockholder's affiliates or to any of Employer's other existing stockholders, and (B) issuances of equity securities of Employer in connection with financings for working capital and other general corporate purposes; and, provided further, that such "Change of Control" qualifies as either a change in ownership of Employer as defined in Section 409A of the Code ("***Section 409A***") or a change in the ownership of a substantial portion of Employer's assets as defined in Section 409A, as the case may be.

3.2.2 Termination by Executive Other than For Good Reason; Termination Upon Non-Renewal by Executive; Termination by Employer for Cause. In the event Executive's employment is terminated by Executive other than for Good Reason

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

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

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

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

(iii) So long as Executive is eligible, and so long as Executive remains eligible, for and upon his timely election of coverage under COBRA, Employer will continue to pay, directly to the healthcare provider when due, Employer's portion of the medical, vision and dental coverage premiums (and Executive will be responsible for Executive's portion) for the COBRA Payment Period; provided that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for the remainder of the COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the COBRA Payment Period, a

fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA Payment Period.

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

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

3.5 Severance Period. "Severance Period" shall mean a period of twelve (12) months beginning on the effective date of Executive's termination of employment with Employer.

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

3.7 Commencement of Severance Payments. The severance payments and benefits set forth in Sections 3.2.1(i) — (iv) (Termination by Employer for Death, Disability, Without Cause, by Executive for Good Reason) and Sections 3.2.3(i) — (iii) (Termination Upon Non-Renewal by Employer) above will not be paid or provided unless Executive executes and does not revoke the Release and the Release is enforceable and effective as provided in the Release on or before the date that is the sixtieth (60th) day following the effective date of termination (such 60th day, the "***Severance Pay Commencement Date***"). No cash severance payments will be paid pursuant to Sections 3.2.1 or 3.2.3 prior to the Severance Pay Commencement Date. On the Severance Pay Commencement Date, Employer will pay in a lump sum the aggregate amount of the cash severance payments that Employer would have paid Executive through such date had the payments commenced on the effective date of termination through the Severance Pay Commencement Date, with the balance paid thereafter on the applicable schedules described above. Notwithstanding any other provision of this Employment Agreement to the contrary, it is intended that the payment of severance upon termination for Good Reason by Executive in

accordance with Section 3.1.7 satisfy the safe harbor set forth in Treasury Regulation Section 1.409A-1(n)(2)(ii)), and any severance payment made pursuant to this Employment Agreement shall satisfy the exemptions from the application of Section 409A of the Code provided under Treasury Regulation Sections 1.409A-1(b)(4), and 1.409A-1 (b)(9).

SECTION 4. CONFIDENTIALITY, INVENTION RIGHTS, NON-COMPETITION AND NON-SOLICITATION

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

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

SECTION 5. MISCELLANEOUS PROVISIONS

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

5.2 Execution in Counterparts. This Employment Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original but all of which taken together shall constitute one and the same agreement (and all signatures need not appear on any one counterpart), and this Employment Agreement shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

5.3 Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed duly given when delivered by hand, or when delivered if mailed by registered or certified mail, postage prepaid, return receipt requested, or private

courier service or via facsimile (with written confirmation of receipt) or email (with written confirmation of receipt) as follows:

If to Employer, to:

Aclaris Therapeutics, Inc.
640 Lee Road, Suite 200
Wayne, PA 19087
Attention: Neal Walker
E-mail: nwalker@aclaristx.com

If to Executive, to the current address on file with Employer,

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

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

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

5.6 Applicable Law. This Employment Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania applicable to contracts made and to be wholly performed therein without regard to its conflicts or choice of law provisions.

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

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

5.9 Waiver, etc. The failure of either of the parties hereto to at any time enforce any of the provisions of this Employment Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way affect the validity of this Employment Agreement or any provision hereof or the right of either of the parties hereto to thereafter

enforce each and every provision of this Employment Agreement. No waiver of any breach of any of the provisions of this Employment Agreement shall be effective unless set forth in a written instrument executed by the party against whom or which enforcement of such waiver is sought, and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.

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

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

5.12 Section 409A of the Code. This Employment Agreement is intended to comply with Section 409A of the Code and its corresponding regulations, or an exemption, and payments may only be made under this Employment Agreement upon an event and in a manner permitted by Section 409A of the Code, to the extent applicable. Payment under this Employment Agreement is intended to be exempt from Code Section 409A under the "short-term deferral" exception set forth in Treasury Regulation Section 1.409A-1(b)(4), to the maximum extent applicable, and then under the "separation pay" exception set forth in Treasury Regulation Section 1.409A-1(b)(9), to the maximum extent applicable. All payments to be made upon a termination of employment under this Employment Agreement may only be made upon a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h) (or any successor provision) (a "***Separation from Service***"). For purposes of Code Section 409A, the right to a series of installment payments under this Employment Agreement shall be treated as a right to a series of separate payments. In no event may the Executive, directly or indirectly, designate the calendar year of a payment. If the termination of employment giving rise to the payments described in Section 3.2.1 is not a Separation from Service, then the amounts otherwise payable pursuant to Section 3.2.1 will instead be deferred without interest and paid when Executive experiences a Separation from Service. Notwithstanding anything in this Employment Agreement to the contrary or otherwise, with respect to any expense, reimbursement or in-kind benefit provided pursuant to this Employment Agreement that constitutes a "deferral of compensation" within the meaning of Section 409A of the Code and its implementing regulations and guidance, (a) the expenses eligible for reimbursement or in-kind benefits provided to Executive must be incurred during the Employment Term (or applicable survival period), (b) the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive in any other calendar year, (c) the reimbursements for expenses for which Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (d) the right to payment or reimbursement or in-kind benefits hereunder may not be liquidated or exchanged for any other benefit. Notwithstanding any provision to the contrary in this Employment Agreement, if Executive

is deemed by Employer at the time of his Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, and if any of the payments due upon Separation from Service set forth herein and/or under any other agreement with Employer are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments will not be provided to Executive prior to the earliest of (i) the expiration of the six (6)-month period measured from the date of Executive's Separation from Service with Employer, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 5.12 will be paid in a lump sum to Executive, and any remaining payments due will be paid as otherwise provided in this Employment Agreement or in the applicable agreement. No interest will be due on any amounts so deferred.

5.13 Section 280G. Notwithstanding any other provision of this Employment Agreement or any other plan, arrangement or agreement to the contrary, if any of the payments or benefits provided or to be provided by Employer or its affiliates to Executive or for Executive's benefit pursuant to the terms of this Employment Agreement or otherwise (the "***Covered Payments***") constitute parachute payments (the "***Parachute Payments***") within the meaning of Section 280G of the Code and, but for this Section 5.13, would be subject to the excise tax imposed under Section 4999 of the Code (or any successor provision thereto) or any similar tax imposed by state or local law or any interest or penalties with respect to such taxes (collectively, the "***Excise Tax***"), then prior to making the Covered Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under clause (i) above is less than the amount under clause (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax. "***Net Benefit***" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes.

(a) Any such reduction shall be made in accordance with Section 409A and the following:

(i) the Covered Payments consisting of cash severance benefits that do not constitute nonqualified deferred compensation subject to Section 409A shall be reduced first, in reverse chronological order; and

(ii) all other Covered Payments consisting of cash payments, and Covered Payments consisting of accelerated vesting of equity based awards to which Treas. Reg. §1.280G-1 Q/A-24(c) does not apply, and that in either case do not constitute nonqualified deferred compensation subject to Section 409A, shall be reduced second, in reverse chronological order; and

(iii) all Covered Payments consisting of cash payments that constitute nonqualified deferred compensation subject to Section 409A shall be reduced third, in reverse chronological order; and

(iv) all Covered Payments consisting of accelerated vesting of equity-based awards to which Treas. Reg. § 1.280G-1 Q/A-24(c) applies shall be the last Covered Payments to be reduced.

(b) Any determination required under this Section 5.13 shall be made in writing in good faith by an independent accounting firm selected by Employer and reasonably acceptable to the Executive (the "***Accountants***"). Employer and Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order to make a determination under this Section 5.13. For purposes of making the calculations and determinations required by this Section 5.13, the Accountants may rely on reasonable, good-faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Accountants' determinations shall be final and binding on Employer and Executive. Employer shall be responsible for all fees and expenses incurred by the Accountants in connection with the calculations required by this Section 5.13.

(c) It is possible that after the determinations and selections made pursuant to this Section 5.13. Executive will receive Covered Payments that are in the aggregate more than the amount intended or required to be provided after application of this Section 5.13 ("***Overpayment***") or less than the amount intended or required to be provided after application of this Section 5.13 ("***Underpayment***").

(i) In the event that: (A) the Accountants determine, based upon the assertion of a deficiency by the Internal Revenue Service against either Employer or Executive that the Accountants believe has a high probability of success, that an Overpayment has been made or (B) it is established pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved that an Overpayment has been made, then Executive shall pay any such Overpayment to Employer together with interest at the applicable federal rate (as defined in Section 7872(f)(2)(A) of the Code) from the date of Executive's receipt of the Overpayment until the date of repayment.

(ii) In the event that: (A) the Accountants, based upon controlling precedent or substantial authority, determine that an Underpayment has occurred or (B) a court of competent jurisdiction determines that an Underpayment has occurred, any such Underpayment will be paid promptly by Employer to or for the benefit of Executive together with interest at the applicable federal rate (as defined in Section 7872(f)(2)(A) of the Code) from the date the amount should have otherwise been paid to Executive until the payment date.

5.14 Dispute Resolution. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the

Executive's employment with the Employer or out of this Employment Agreement, or the Executive's termination of employment or termination of this Employment Agreement, may not be in the best interests of either the Executive or Employer, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Employment Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Employment Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Executive Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided however,* that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the Philadelphia, Pennsylvania metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by Employer. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Employment Agreement and continue after the termination of the employment relationship between Executive and Employer. The parties each further agree that the arbitration provisions of this Employment Agreement shall provide each party with its **exclusive remedy,** and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Employment Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Employment Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.**

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF the parties have executed this Employment Agreement as of the date first above written.

ACLARIS THERAPEUTICS, INC.

/s/ Neal Walker

Name: Neal Walker
Title President & CEO

Agreed to and Accepted this 12th day of January, 2022.

EXECUTIVE

/s/ Joe Monahan

Joseph Monahan

Exhibit A

List of Entities Referenced in Section 1.2.2.

Cadre Bioscience, LLC
Myonid Therapeutics, LLC

EMPLOYMENT AGREEMENT

This EMPLOYMENT AGREEMENT (the "***Employment Agreement***"), effective as of January 31, 2022 ("***Agreement Effective Date***"), is made by and between Aclaris Therapeutics, Inc., a corporation organized under the laws of the State of Delaware ("***Employer***") and James Loerop ("***Executive***").

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

WHEREAS, Employer and Executive desire to formalize the terms and conditions of Executive's employment with Employer; and

WHEREAS, this Employment Agreement has been duly approved and its execution has been duly authorized by the Employer's Board of Directors (the "***Board***").

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

SECTION 1. EMPLOYMENT

1.1 General. Employer hereby agrees to employ Executive in the capacity of Chief Business Officer ("***CBO***"). Executive hereby accepts such employment upon the terms and subject to the conditions herein contained.

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

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

1.2.2 Time to Be Devoted to Employment. During Executive's Employment with Employer, Executive shall diligently devote his efforts, business time, attention and energies to the business of Employer and will not, while employed by Employer, undertake or engage in any other employment, occupation or business enterprise that would interfere with Executive's responsibilities and the performance of Executive's duties hereunder except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Executive may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Executive's duties; and (iii) reasonable time devoted to service as a member of the board of directors of the entities listed on Exhibit A or as otherwise permitted pursuant to Section 1.3. This restriction shall not, however, preclude Executive (x) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (y) from employment or service in any capacity with Affiliates of Employer. As used in this Employment Agreement, "Affiliates" means an entity under common management or control with Employer.

1.3 Other Responsibilities. Notwithstanding Section 1.2.2 above, Executive will not engage in any other for-profit business, profession or occupation, including as a member of a board of directors of any third party, for compensation which would materially conflict or materially interfere with the rendition of services hereunder, without the prior written consent of the Board, which shall not be unreasonably withheld. Any uncertainty as to whether such a conflict exists will be raised by Executive for determination by the Board, acting reasonably. The Board acknowledges that Executive has ongoing participation in other private and public businesses that have been disclosed by Executive and are listed on Exhibit A and that such participation does not, in any way, conflict with his role at Employer. Except for the businesses listed on Exhibit A, which have already been approved, Executive agrees to disclose to the Board and receive prior written consent from the Board to participate as a director, with any competing company whether it is a private or public company. Executive further agrees to disclose any other director positions with any other company that may materially affect his ability to perform his duties and responsibilities under this Employment Agreement. Notwithstanding the above, nothing herein shall limit or preclude Executive from managing any passive investments made by Executive.

1.4 Location of Employment. Executive's principal place of employment during his employment with Employer shall be Executive's primary residence (or other remote work location) or such other location as Employer and Executive shall agree; provided however, that from time to time Executive may be required to travel to Employer's principal executive office currently located in Wayne, Pennsylvania.

SECTION 2. COMPENSATION AND BENEFITS

2.1 Salary. Employer will pay to Executive an annual base salary of $416,000 payable subject to standard federal and state payroll withholding requirements in accordance with the regular payroll practices of Employer ("***Base Salary***"). The annual Base Salary may be increased (but not decreased) during the term of this Employment Agreement by the Board in its sole discretion.

2.2 Additional Compensation. In addition to the salary set forth in Section 2.1, Executive shall be entitled to receive a cash bonus in accordance with the terms of this Section 2.2. For each fiscal year of Employer, beginning January 1, during the Employment Term (as defined in Section 2.4 hereof), Executive shall be eligible to receive a cash bonus based on (i) the "***Annual Bonus Expectancy Amount***," which shall be an amount equal to 40% of Executive's Base Salary for the applicable fiscal year, and (ii) Executive's attainment of performance targets and other reasonable criteria established by the Board, to the extent possible, by the end of the first month of such fiscal year. Depending on the targets and criteria which are achieved or met, the amount of the cash bonus actually payable to Executive for each fiscal year will be an amount from zero to and including the Annual Bonus Expectancy Amount. Any cash bonus amount payable pursuant to this Section 2.2 shall be paid to Executive as soon as practicable, but in no event later than two and one-half (2 1/2) months, following the end of the fiscal year to which it relates. For the avoidance of doubt, Executive does not have to be employed by Employer on the date such bonus is approved or paid by Employer to receive such bonus.

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

2.3.1 Expenses. Employer will promptly reimburse Executive for expenses he reasonably incurs in connection with the performance of his duties (including business travel and entertainment expenses), in accordance with Employer's standard expense reimbursement policy, as the same may be modified by Employer from time to time; provided, however, that Executive has provided Employer with documentation of such expenses in accordance with the Employer's expense reimbursement policies and applicable tax requirements. For the avoidance of doubt, to the extent that any reimbursements payable to Executive are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"): (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Employment Agreement will not be subject to liquidation or exchange for another benefit.

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

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

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

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

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

the other party at least ninety (90) days prior to expiration of the Initial Term or the Renewal Term.

SECTION 3. TERMINATION OF EMPLOYMENT

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

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

3.1.2 Disability. In the event of Executive's Disability (as hereinafter defined), Employer will have the option to terminate Executive's employment by giving a notice of termination to Executive. The notice of termination shall specify the date of termination, which date shall not be earlier than thirty (30) calendar days after the notice of termination is given. For purposes of this Employment Agreement, "***Disability***" has the meaning set forth in Employer's long term disability plan.

3.1.3 Termination by Employer for Cause. Employer may, at its option, terminate Executive's employment for Cause (as hereinafter defined) by unilateral action of the Board of Directors upon giving a notice of termination to Executive. "***Cause***" shall mean (i) Executive's conviction of, or guilty plea to, a felony (other than traffic violations); (ii) any act(s) or omission(s) by Executive which constitutes gross negligence or a material breach of Executive's duty of loyalty; (iii) any material breach by Executive of Employer's personnel policies; (iv) refusal to follow or implement a clear and reasonable directive of Employer; (v) breach of fiduciary duty; or (vi) a material violation or breach by Executive of this Employment Agreement (other than an event described in the foregoing clauses) or any other agreement between the parties.

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

3.1.5 By Executive. Executive may, at any time, terminate Executive's employment for any reason whatsoever by giving a notice of termination to Employer. Executive's employment shall terminate on the earlier of (i) thirty (30) calendar days after the date of receipt by Employer of the notice of termination or (ii) such earlier date as the Employer and Executive shall agree.

3.1.6 Termination Upon Non-Renewal. Either party may terminate this Employment Agreement and Executive's employment hereunder by providing the other party notice in accordance with Section 2.4 above, in which case this Employment Agreement and Executive's employment hereunder shall terminate on the last date of the Initial Term or the Renewal Term, as the case may be. For the avoidance of doubt, Executive shall continue to be employed by Employer, on the same terms and conditions as set forth in this Employment

Agreement during the ninety (90)-day notice period provided by either party to the other party in accordance with Section 2.4 above, unless, Employer, in its sole discretion determines that it does not want Executive to continue to work for Employer, in any capacity, during such notice period. In such event, Employer shall pay Executive all compensation in accordance with Section 3.2.3.

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

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

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

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

(iv) Executive's place of employment is changed to a location that is greater than fifty (50) miles from Executive's current place of employment (disregarding for this purpose any remote work arrangements); or

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

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

3.2.1 Death; Disability; Termination by Employer Without Cause or by Executive for Good Reason. In the event that Executive's employment is terminated by Employer pursuant to Section 3.1.1 ("***Death***"), Section 3.1.2 ("***Disability***"), Section 3.1.4 ("***Without Cause by Employer***") or by Executive pursuant to Section 3.1.7 ("***Termination by***

Executive for Good Reason") hereof, and Executive, or his estate, as the case may be, executes and does not revoke a separation agreement containing a release upon such termination, in a form provided by the Employer, of any and all claims against Employer and all related parties with respect to all matters arising out of Executive's employment by Employer, or the termination thereof (the "***Release***") in accordance with Section 3.7, Executive, or his estate, as the case may be, shall be entitled to the following payments and benefits, which payments and benefits shall be paid in accordance with this Section 3.2.1 and Section 3.7:

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

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

(iii) So long as Executive is eligible, and so long as Executive remains eligible, for and upon his timely election of coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or, if applicable, state or local insurance laws ("***COBRA***"), Employer will continue to pay, directly to the healthcare provider when due, Employer's portion of the medical, vision and dental coverage premiums (and Executive will be responsible for Executive's portion) for a period of twelve (12) months after the effective date of Executive's termination (the "***COBRA Payment Period***"); provided that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for the remainder of the COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA Payment Period; and

(iv) In the event such termination of employment occurs on or within three (3) months prior to or within twelve (12) months following the effective date of a Change of Control (as defined herein), Executive shall be entitled to the <u>additional</u> following payments and benefits (for the avoidance of doubt, Executive shall also be entitled to the amounts set forth in Section 3.2.1(i)-(iii)):

(1) Employer shall pay to Executive a lump sum payment equal to the Annual Expectancy Bonus Amount (target bonus), less applicable deductions and withholdings, paid within thirty (30) days of the later of (a) the effective date of the Change of Control or (b) Executive's termination, if such termination occurs on or after the effective date of a Change of Control; and

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

For purposes of this Employment Agreement, "***Change of Control***" means, in each case as approved by the Board and the requisite stockholders of Employer, (i) any consolidation or merger of Employer with or into any other corporation or other entity or person, or any other corporate reorganization, in which the stockholders of Employer immediately prior to such consolidation, merger or reorganization, own, in the aggregate, less than 50% of the surviving entity's voting power and/or outstanding capital stock immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions (including any transaction which results from an option agreement or binding letter of intent with a third party) to which Employer or any of its stockholders is a party in which in excess of 50% of Employer's voting power and/or outstanding capital stock is transferred, or pursuant to which any person or group of affiliated persons obtains in excess of 50% of Employer's voting power and/or outstanding capital stock, excluding any consolidation or merger effected exclusively to change the domicile of Employer; or (ii) any sale, license or other disposition (including through a Board and stockholder approved division or spin-off transaction) of all or substantially all of the assets of Employer and/or any of its subsidiaries or any sale, exclusive license or other disposition of all or substantially all of Employer's intellectual property, as reasonably determined based upon the potential earning power of the assets or intellectual property; provided, however, that none of the following shall constitute a Change of Control: (A) transfers of capital stock by an existing stockholder as a result of death or otherwise for estate planning purposes or to such stockholder's affiliates or to any of Employer's other existing stockholders, and (B) issuances of equity securities of Employer in connection with financings for working capital and other general corporate purposes; and, provided further, that such "Change of Control" qualifies as either a change in ownership of Employer as defined in Section 409A of the Code ("***Section 409A***") or a change in the ownership of a substantial portion of Employer's assets as defined in Section 409A, as the case may be.

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

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

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

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

(iii) So long as Executive is eligible, and so long as Executive remains eligible, for and upon his timely election of coverage under COBRA, Employer will continue to pay, directly to the healthcare provider when due, Employer's portion of the medical, vision and dental coverage premiums (and Executive will be responsible for Executive's portion) for the COBRA Payment Period; provided that, if at any time Employer determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of the nondiscrimination rules of Section 105(h)(2) of the Code or any statute or regulation of similar effect (including but not limited to the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of providing the COBRA premiums for

the remainder of the COBRA Payment Period, Employer will instead pay Executive on the first day of each month of the remainder of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the remainder of the COBRA Payment Period.

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

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

3.5 Severance Period. "Severance Period" shall mean a period of twelve (12) months beginning on the effective date of Executive's termination of employment with Employer.

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

3.7 Commencement of Severance Payments. The severance payments and benefits set forth in Sections 3.2.1(i) — (iv) (Termination by Employer for Death, Disability, Without Cause, by Executive for Good Reason) and Sections 3.2.3(i) — (iii) (Termination Upon Non-Renewal by Employer) above will not be paid or provided unless Executive executes and does not revoke the Release and the Release is enforceable and effective as provided in the Release on or before the date that is the sixtieth (60th) day following the effective date of termination (such 60th day, the "***Severance Pay Commencement Date***"). No cash severance payments will be paid pursuant to Sections 3.2.1 or 3.2.3 prior to the Severance Pay Commencement Date. On the Severance Pay Commencement Date, Employer will pay in a lump sum the aggregate amount of the cash severance payments that Employer would have paid Executive through such date had the payments commenced on the effective date of termination through the Severance Pay Commencement Date, with the balance paid thereafter on the applicable schedules described

above. Notwithstanding any other provision of this Employment Agreement to the contrary, it is intended that the payment of severance upon termination for Good Reason by Executive in accordance with Section 3.1.7 satisfy the safe harbor set forth in Treasury Regulation Section 1.409A-1(n)(2)(ii)), and any severance payment made pursuant to this Employment Agreement shall satisfy the exemptions from the application of Section 409A of the Code provided under Treasury Regulation Sections 1.409A-1(b)(4), and 1.409A-1 (b)(9).

SECTION 4. CONFIDENTIALITY, INVENTION RIGHTS, NON-COMPETITION AND NON-SOLICITATION

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

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

SECTION 5. MISCELLANEOUS PROVISIONS

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

5.2 Execution in Counterparts. This Employment Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original but all of which taken together shall constitute one and the same agreement (and all signatures need not appear on any one counterpart), and this Employment Agreement shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Counterparts may be delivered via facsimile, electronic mail (including pdf or any electronic signature complying with the U.S. federal ESIGN Act of 2000, Uniform Electronic Transactions Act or other applicable law) or other transmission method and any counterpart so delivered will be deemed to have been duly and validly delivered and be valid and effective for all purposes.

5.3 Notices. All notices, requests, demands and other communications hereunder shall be in writing and shall be deemed duly given when delivered by hand, or when delivered if

mailed by registered or certified mail, postage prepaid, return receipt requested, or private courier service or via facsimile (with written confirmation of receipt) or email (with written confirmation of receipt) as follows:

If to Employer, to:

Aclaris Therapeutics, Inc.
640 Lee Road, Suite 200
Wayne, PA 19087
Attention: Neal Walker
E-mail: nwalker@aclaristx.com

If to Executive, to the current address on file with Employer,

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

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

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

5.6 Applicable Law. This Employment Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania applicable to contracts made and to be wholly performed therein without regard to its conflicts or choice of law provisions.

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

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

5.9 Waiver, etc. The failure of either of the parties hereto to at any time enforce any of the provisions of this Employment Agreement shall not be deemed or construed to be a

waiver of any such provision, nor to in any way affect the validity of this Employment Agreement or any provision hereof or the right of either of the parties hereto to thereafter enforce each and every provision of this Employment Agreement. No waiver of any breach of any of the provisions of this Employment Agreement shall be effective unless set forth in a written instrument executed by the party against whom or which enforcement of such waiver is sought, and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.

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

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

5.12 Section 409A of the Code. This Employment Agreement is intended to comply with Section 409A of the Code and its corresponding regulations, or an exemption, and payments may only be made under this Employment Agreement upon an event and in a manner permitted by Section 409A of the Code, to the extent applicable. Payment under this Employment Agreement is intended to be exempt from Code Section 409A under the "short-term deferral" exception set forth in Treasury Regulation Section 1.409A-1(b)(4), to the maximum extent applicable, and then under the "separation pay" exception set forth in Treasury Regulation Section 1.409A-1(b)(9), to the maximum extent applicable. All payments to be made upon a termination of employment under this Employment Agreement may only be made upon a "separation from service" within the meaning of Treasury Regulation Section 1.409A-1(h) (or any successor provision) (a "***Separation from Service***"). For purposes of Code Section 409A, the right to a series of installment payments under this Employment Agreement shall be treated as a right to a series of separate payments. In no event may the Executive, directly or indirectly, designate the calendar year of a payment. If the termination of employment giving rise to the payments described in Section 3.2.1 is not a Separation from Service, then the amounts otherwise payable pursuant to Section 3.2.1 will instead be deferred without interest and paid when Executive experiences a Separation from Service. Notwithstanding anything in this Employment Agreement to the contrary or otherwise, with respect to any expense, reimbursement or in-kind benefit provided pursuant to this Employment Agreement that constitutes a "deferral of compensation" within the meaning of Section 409A of the Code and its implementing regulations and guidance, (a) the expenses eligible for reimbursement or in-kind benefits provided to Executive must be incurred during the Employment Term (or applicable survival period), (b) the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive during any calendar year will not affect the amount of expenses eligible for reimbursement or in-kind benefits provided to Executive in any other calendar year, (c) the reimbursements for expenses for which Executive is entitled to be reimbursed shall be made on or before the last day of the calendar year following the calendar year in which the applicable expense is incurred and (d) the right to payment or reimbursement or

in-kind benefits hereunder may not be liquidated or exchanged for any other benefit. Notwithstanding any provision to the contrary in this Employment Agreement, if Executive is deemed by Employer at the time of his Separation from Service to be a "specified employee" for purposes of Section 409A(a)(2)(B)(i) of the Code, and if any of the payments due upon Separation from Service set forth herein and/or under any other agreement with Employer are deemed to be "deferred compensation," then to the extent delayed commencement of any portion of such payments is required to avoid a prohibited distribution under Section 409A(a)(2)(B)(i) of the Code and the related adverse taxation under Section 409A of the Code, such payments will not be provided to Executive prior to the earliest of (i) the expiration of the six (6)-month period measured from the date of Executive's Separation from Service with Employer, (ii) the date of Executive's death or (iii) such earlier date as permitted under Section 409A of the Code without the imposition of adverse taxation. Upon the first business day following the expiration of such applicable Code Section 409A(a)(2)(B)(i) period, all payments deferred pursuant to this Section 5.12 will be paid in a lump sum to Executive, and any remaining payments due will be paid as otherwise provided in this Employment Agreement or in the applicable agreement. No interest will be due on any amounts so deferred.

5.13 Section 280G. Notwithstanding any other provision of this Employment Agreement or any other plan, arrangement or agreement to the contrary, if any of the payments or benefits provided or to be provided by Employer or its affiliates to Executive or for Executive's benefit pursuant to the terms of this Employment Agreement or otherwise (the "***Covered Payments***") constitute parachute payments (the "***Parachute Payments***") within the meaning of Section 280G of the Code and, but for this Section 5.13, would be subject to the excise tax imposed under Section 4999 of the Code (or any successor provision thereto) or any similar tax imposed by state or local law or any interest or penalties with respect to such taxes (collectively, the "***Excise Tax***"), then prior to making the Covered Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to Executive of the Covered Payments after payment of the Excise Tax to (ii) the Net Benefit to Executive if the Covered Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under clause (i) above is less than the amount under clause (ii) above will the Covered Payments be reduced to the minimum extent necessary to ensure that no portion of the Covered Payments is subject to the Excise Tax. "***Net Benefit***" shall mean the present value of the Covered Payments net of all federal, state, local, foreign income, employment and excise taxes.

(a) Any such reduction shall be made in accordance with Section 409A and the following:

(i) the Covered Payments consisting of cash severance benefits that do not constitute nonqualified deferred compensation subject to Section 409A shall be reduced first, in reverse chronological order; and

(ii) all other Covered Payments consisting of cash payments, and Covered Payments consisting of accelerated vesting of equity based awards to which Treas. Reg. §1.280G-1 Q/A-24(c) does not apply, and that in either

case do not constitute nonqualified deferred compensation subject to Section 409A, shall be reduced second, in reverse chronological order; and

(iii) all Covered Payments consisting of cash payments that constitute nonqualified deferred compensation subject to Section 409A shall be reduced third, in reverse chronological order; and

(iv) all Covered Payments consisting of accelerated vesting of equity-based awards to which Treas. Reg. § 1.280G-1 Q/A-24(c) applies shall be the last Covered Payments to be reduced.

(b) Any determination required under this Section 5.13 shall be made in writing in good faith by an independent accounting firm selected by Employer and reasonably acceptable to the Executive (the "***Accountants***"). Employer and Executive shall provide the Accountants with such information and documents as the Accountants may reasonably request in order to make a determination under this Section 5.13. For purposes of making the calculations and determinations required by this Section 5.13, the Accountants may rely on reasonable, good-faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Accountants' determinations shall be final and binding on Employer and Executive. Employer shall be responsible for all fees and expenses incurred by the Accountants in connection with the calculations required by this Section 5.13.

(c) It is possible that after the determinations and selections made pursuant to this Section 5.13. Executive will receive Covered Payments that are in the aggregate more than the amount intended or required to be provided after application of this Section 5.13 ("***Overpayment***") or less than the amount intended or required to be provided after application of this Section 5.13 ("***Underpayment***").

(i) In the event that: (A) the Accountants determine, based upon the assertion of a deficiency by the Internal Revenue Service against either Employer or Executive that the Accountants believe has a high probability of success, that an Overpayment has been made or (B) it is established pursuant to a final determination of a court or an Internal Revenue Service proceeding that has been finally and conclusively resolved that an Overpayment has been made, then Executive shall pay any such Overpayment to Employer together with interest at the applicable federal rate (as defined in Section 7872(f)(2)(A) of the Code) from the date of Executive's receipt of the Overpayment until the date of repayment.

(ii) In the event that: (A) the Accountants, based upon controlling precedent or substantial authority, determine that an Underpayment has occurred or (B) a court of competent jurisdiction determines that an Underpayment has occurred, any such Underpayment will be paid promptly by Employer to or for the benefit of Executive together with interest at the applicable federal rate (as defined in Section 7872(f)(2)(A) of the Code) from the date the amount should have otherwise been paid to Executive until the payment date.

5.14 Dispute Resolution. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Executive's employment with the Employer or out of this Employment Agreement, or the Executive's termination of employment or termination of this Employment Agreement, may not be in the best interests of either the Executive or Employer, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Employment Agreement or the Executive's employment, including, but not limited to, any claim arising out of this Employment Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Executive Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided however,* that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy. The location for the arbitration shall be the Philadelphia, Pennsylvania metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by Employer. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Employment Agreement and continue after the termination of the employment relationship between Executive and Employer. The parties each further agree that the arbitration provisions of this Employment Agreement shall provide each party with its **exclusive remedy,** and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Employment Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Employment Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.**

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF the parties have executed this Employment Agreement as of the date first above written.

ACLARIS THERAPEUTICS, INC.

/s/ Neal Walker

Name: Neal Walker
Title President & CEO

Agreed to and Accepted this 26th day of January, 2022.

EXECUTIVE

/s/ James Loerop

James Loerop

1/26/2022

Exhibit A

List of Entities Referenced in Section 1.2.2.

None.

November 1, 2021

RE: Severance Agreement and General Release

Dear

This letter is intended to set forth the terms of your separation from employment with Aclaris Therapeutics, Inc. and your general release and waiver of claims in favor of Aclaris Therapeutics, Inc., and its parents, subsidiaries, affiliates, and all related corporate entities and partnerships, and their current or former officers, directors, partners, shareholders, members, representatives, agents, employees, predecessors, successors, and assigns ("Aclaris").

The terms of this Severance Agreement and General Release ("Agreement") are as follows, and you and Aclaris, intending to be legally bound and for good and valuable consideration, each agree to all of the following terms:

1. Your Termination from Employment. Your retirement from Aclaris will be effective as of January 3, 2022 (the "Retirement Date"). Aclaris will pay all compensation due and owing to you as of the Retirement Date, in accordance with its usual compensation and payroll practices.

2. Separation Pay and Benefits.

a. Severance Pay. Subject to the terms of this Agreement, you will be entitled to receive a severance payment comprised of the following: (i) $391,400 constituting the total gross amount via direct deposit on January 3, 2022 for twelve (12) months' salary based on your current base salary; (ii) $156,560 constituting the total gross amount of your 2021 bonus via direct deposit on January 3, 2022; (iii) accelerated vesting of 34,788 unvested restricted stock units awarded to you, in connection with your employment with Aclaris from Grant Nos. 185, 459, 700, and 784 on February 1, 2018, March 1, 2019, March 2, 2020, and March 1, 2021 and accelerated vesting of and extension of the exercise period applicable to 61,607 unvested options awarded to you, in connection with your employment with Aclaris from Grant Nos. 2080, 675, and 687 on February 1, 2018, March 2, 2020, and March 1, 2021 such that all such restricted stock unit awards and options in subparagraph (iii) shall be fully vested. In addition, the exercise period for all currently vested and accelerated vested options shall be extended from ninety (90) days to one hundred eighty (180) days from the Retirement Date; (iv) accelerated vesting of such number of additional unvested restricted stock units awarded to you, in connection with your employment with Aclaris, from Grant No. 459 on March 1, 2019 equal to a value of $156,560, determined by such value divided by the closing price of Aclaris common stock on the Retirement Date and which shall be accelerated so that as of the Retirement Date all such unvested restricted stock units shall be fully vested, and (v) so long as you are eligible, and so long as you remain eligible, for and upon your timely election of coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or, if applicable, state or local insurance laws ("COBRA"), Aclaris will continue to pay, directly to the healthcare provider when due, 100% of the medical, vision and dental coverage premiums for family coverage (including employee contributions, if any) until twelve (12) months from January 31, 2022 (the "COBRA Payment Period"); and provided further that, if at any time Aclaris determines, in its sole discretion, that the payment of the COBRA premiums would result in a violation of any nondiscrimination rules applicable under the Internal Revenue Code or otherwise, then in lieu of providing the COBRA premiums for the remainder of the COBRA Payment Period, Aclaris will instead pay you on the first day of each month of the remainder of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premiums for that month, subject to applicable tax withholdings, for the

remainder of the COBRA Payment Period (subparagraphs (i), and (iii) – (v), collectively referred to as "Severance Payment"). The cash portion of your Severance Payment will be paid in one lump sum via direct deposit on January 3, 2022. Aclaris will deduct all normal tax withholdings and deductions required by law from all payment amounts under this Agreement. Your direct deposit statements will be sent to your home address via United States first class mail or by email to your personal email address. The Severance Payment specified in this paragraph is the only severance payment to which you will be entitled.

b. Timing of Cash Severance Payment. The cash portion of your Severance Payment will be paid in one lump sum on January 3, 2022. Notwithstanding any other provision of this Agreement to the contrary, it is intended that any Severance Payment made pursuant to this Agreement shall satisfy the exemptions from the application of Section 409A of the Code, including those provided under Treasury Regulation Sections 1.409A-1(b)(4), and 1 .409A-1 (b)(9).

c. Accrued and Unused Vacation Time. You will also be paid $67,742.32 which constitutes nine (9) weeks of unused vacation time in one lump sum via direct deposit on January 3, 2022. Aclaris will deduct all normal tax withholdings and deductions required by law. Your direct deposit statements will be sent to your home address via United States first class mail or by email to your personal email address.

d. Benefit Continuation. Aclaris will terminate your health, dental and vision coverages effective as of January 31, 2022. After January 31, 2022, you may elect to continue your health, dental and vision family coverages under COBRA for up to a balance of eighteen (18) months. In order to receive this COBRA benefit, you must complete and return the COBRA election paperwork, which will be sent to your home or emailed to your personal email address approximately two (2) weeks after your loss of benefit coverage. After the expiration of the COBRA Payment Period, you will be fully responsible for payment of the premium cost of your family COBRA coverage, if elected. All other benefits will be terminated effective as of the Retirement Date. Your rights to any portability or conversion options with regard to your benefits will be mailed to your home or emailed to your personal email address in accordance with Aclaris' usual policies and/or practices.

e. Contingent Nature of Compensation. The Severance Payment under this Agreement shall not be paid unless you have signed and do not revoke this Agreement pursuant to Paragraphs 21 and 22 below, and provided that such payment will further be contingent upon your continued satisfaction of your covenants set forth in Paragraphs 4, 5 and 6 of this Agreement and your continued compliance with all of your legal duties and contractual obligations to Aclaris, including, without limitation, all obligations under this Agreement.

f. Savings Plan. You will be entitled to any vested amounts held by you or on your account in Aclaris' 401(k) savings plan, such amounts to be distributed to you or on your account in accordance with the plan terms and/or as required by applicable law.

g. No Other Compensation or Benefits. The compensation and benefits specified in this Paragraph 2 are the only compensation and benefits to which you will be entitled, and no other compensation or benefits of any kind shall be provided to you. You acknowledge that you are not due or entitled to any salary, benefits, or payments of any kind from Aclaris that are not specified in this Agreement.

3. Acknowledgment of Consideration. You acknowledge that, in return for executing this Agreement, particularly the general release in Paragraph 7, you are receiving satisfactory and adequate consideration to which you would not otherwise be entitled.

4. Transition and Cooperation.

a. Transition. You will fully cooperate with Aclaris to affect a professional, cooperative transition of your work and responsibilities.

b. Future Cooperation with Aclaris and its Counsel. You will, upon Aclaris' reasonable request, cooperate to the best of your ability with Aclaris and with any legal counsel, expert, or consultant it may retain to assist it in connection with any judicial proceeding, arbitration, administrative proceeding, governmental investigation or inquiry, internal investigation, or audit in which Aclaris is or becomes involved. This includes, but is not limited to, your assistance, cooperation, and participation with respect to any matter in which you have information relevant to the inquiry, or in which you are identified as a witness. Your assistance, cooperation and participation include, without limitation, preparing for and attending depositions, assisting in answering factual questions for discovery, and preparing for and attending any hearing or trial as a witness. Aclaris agrees to reimburse you for any reasonable out of pocket expenses incurred as a result of your assistance, cooperation and participation. In addition, Aclaris will pay you a reasonable amount of compensation as agreed by the parties in good faith as compensation for the time and effort required in providing the requested assistance. You will promptly notify Aclaris if you are subpoenaed by any person or entity (including, but not limited to, any governmental agency) to give information or testimony that in any way relates to your employment with or representation of Aclaris. You will testify truthfully in all such matters or proceedings. Nothing in this Agreement is intended to be or may be construed in any way as being dependent upon or contingent on the content of your testimony.

5. Confidentiality. You agree to the following terms relating to confidentiality:

a. Confidentiality: Return of Property. You agree to return promptly to Aclaris all company keys, cards, materials, laptop computers and other company property, including without limitation, all confidential and/or proprietary business, financial or technical information such as, without limitation, writings, documents, manuals, notebooks, reports, audio/video work, inventions, formulas, processes, technical know-how, machines, compositions, computer software, microfiche, accounting methods, business plans and information systems including such materials, information and data which are in machine readable form or otherwise and any information gained through discussions and/or meetings, etc. of Aclaris, if you have not done so already, and you further agree not to reveal any confidential and/or proprietary business, financial or technical information to any other person or entity or to use such information for your benefit or the benefit of anyone else, either during or subsequent to your employment with Aclaris, without the prior written approval of Aclaris. Notwithstanding the foregoing, you may keep certain personal computer and office equipment, for no additional consideration.

b. Confidentiality: Non-Disclosure. You agree not to use, publish, or otherwise disclose any secret or confidential information or data of Aclaris or any information or data of others, which Aclaris is obligated to maintain in confidence. However, you shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (1) is made (a) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and (b) solely for the purpose of reporting or investigating a suspected violation of law; (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; or (3) is or becomes a matter of public record without any breach of the terms of this Agreement by you. Disclosures to attorneys, made under seal, or pursuant to court order are also protected in certain circumstances under 18 U.S.C. 1833.

c. Confidentiality of the Agreement. You agree to keep this Agreement and its terms strictly confidential and not disclose this information to any third party (including any past, present, or future employees of Aclaris) other than your accountant, legal representative, and immediate family who also agree to keep this matter strictly

confidential, except as directed by court order. The terms of this Agreement may be disclosed in an arbitration to enforce the terms as provided in Paragraph 14 below.

6. Non-Disparagement. You agree not to, in any manner whatsoever, directly, or indirectly, disparage Aclaris or any of its officers, directors, employees, agents, customers, products, or any aspects of Aclaris' business. Aclaris agrees to instruct all employees including Neal Walker, President and Chief Executive Officer, Frank Ruffo, Chief Financial Officer, Joe Monahan, Chief Scientific Officer, and David Gordon, Chief Medical Officer, as long as they are employed by Aclaris, not to, in any manner whatsoever, directly or indirectly, disparage you.

7. General Release.

a. Except as noted below in Paragraph 12, you hereby generally release and discharge Aclaris from any and all suits, causes of action, complaints, charges, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown (hereinafter "claims"), which you ever had or now have against Aclaris arising out of or relating to any matter, thing or event occurring up to and including the date of this Agreement. You also release Aclaris from any and all claims for wrongful discharge, defamation, unfair treatment, violation of public policy, breach of express or implied contract, intentional or negligent infliction of emotional distress, any and all tort claims or any other claim related to your employment with Aclaris or the termination of that employment for any and all reasons, up to and including the date of this Agreement. You specifically release Aclaris from any claim relating to or arising out of your employment with or termination of employment from Aclaris, including, but not limited to, any rights or claims you may have based upon Title VII of the Civil Rights Act of 1964, as amended, which prohibits discrimination in employment based on race, color, creed, religion, national origin or sex; the Age Discrimination in Employment Act including the Older Workers Benefits Protection Act ("ADEA"), which prohibits discrimination on the basis of age; the Equal Pay Act, which prohibits paying men and women unequal pay for equal work; the Americans with Disabilities Act of 1990, as amended, which prohibits discrimination against disabled persons; the Family Medical Leave Act, as amended, which permits extended time away from work to handle certain family or medical needs; the Employee Retirement Income Security Act, which regulates employment benefits; the Pennsylvania Human Relations Act, which prohibits discrimination in employment based on race, color, religion, sex, disability, national origin, age, or the results of genetic testing; the False Claims Act, 31 U.S.C. § § 3729-3733 (including the qui tam provision thereof); the Consolidated Omnibus Budget Reconciliation Act of 1986; the Rehabilitation Act of 1973; the Electronic Communications Privacy Act of 1986 (including the Stored Communications Act); the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); and any and all other federal, state or local laws or regulations prohibiting employment discrimination or which otherwise regulate employment terms and conditions, except as such release is limited by applicable laws. This is a general release and covers claims that you know about presently and those that you may not know about up through the date of this Agreement. This release specifically includes any and all claims for attorney's fees and costs which you incur for any reason arising out of or relating to any or all matters covered by this Agreement.

b. You hereby represent and warrant that you have no knowledge of any acts or omissions by Aclaris or any other party released herein that are or could be construed as a breach or violation of the federal and state employment laws administered by the Equal Employment Opportunity Commission or any comparable state or local fair employment practices agencies, or of the National Labor Relations Act, 29 U.S.C. § 157, or of the False Claims Act, 31 U.S.C. § § 3729-3733, or of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Nothing in this Agreement should be construed as prohibiting you from responding to inquiries from or otherwise reporting possible violations of federal or state law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation. However, by signing this Agreement you hereby waive and release any and all right to benefit personally or monetarily as a result of any such inquiry,

complaint, or investigation. This paragraph applies to all claims you could have brought prior to the date of this Agreement and is a material inducement of this Agreement.

8. No Admission. This Agreement represents a full, complete, and binding compromise of claims and shall not be construed as an admission by any party of any liability or of any contention or allegation made by the other party.

9. References. In accordance with Aclaris' usual policies, when responding to requests related to your future employment or references for you, Aclaris will provide only information regarding your employment start date, Retirement Date, and job titles. Any such requests should be directed to Frank Ruffo, Chief Financial Officer.

10. Employment Termination Acknowledgment. You confirm that your employment with Aclaris terminates effective on the Retirement Date, and that Aclaris has settled all obligations to you (except with respect to Aclaris' obligations under this Agreement). You agree to waive any claim to future employment with Aclaris. You further agree that you will not, at any time in the future, apply for or seek any type of employment with Aclaris, provided that at Aclaris' request, you may be employed as a consultant for Aclaris. If you do so, you hereby acknowledge that Aclaris' refusal to hire you or subsequent termination of your employment, will be legitimately based upon this provision and not for some other, unlawful reason.

11. No Pending Claims. You acknowledge that you have not filed a lawsuit in any federal or state court or initiated any other governmental, administrative, or regulatory proceeding or investigation against Aclaris, and that you have not assigned any claim against Aclaris to any other person or entity.

12. Promise Not to Sue. You promise never to file any claim, complaint, demand for arbitration, or lawsuit against Aclaris or allow any other party acting on your behalf to do so based on or asserting any claims relating to your employment with Aclaris, your termination of employment with Aclaris, or any of the claims released herein. Notwithstanding the broad scope of the general release above in Paragraph 7, this Agreement is not intended to bar any claims that, as a matter of law, whether by statute or otherwise, may not be waived, such as claims for workers' compensation benefits, unemployment insurance benefits and any challenge to the validity of your general release of claims under the ADEA as set forth in this Agreement and Release. Nothing in this Agreement is intended to interfere with your right to file a charge or participate in an administrative investigation or proceeding; any claims by you (or on your behalf) for personal relief including, without limitation, reinstatement, or monetary damages, would be barred. You specifically understand that, in the event a complaint or charge is filed, you shall personally have no right to any relief whatsoever against Aclaris, including having no right to reinstatement, monetary damages or attorneys' fees.

13. Forfeiture. If you breach this Agreement, including but not limited to the provisions of Paragraphs 4 through 6 hereof, the compensation contained in Paragraph 2 of this Agreement shall be forfeited and Aclaris shall have no obligation to pay any amount other than your final salary as of the Retirement Date and any other amounts that may be required by law to be paid. In addition, if you breach this Agreement after payment hereunder has been made, Aclaris shall be entitled to have the payment refunded pursuant to an adjudication under Paragraph 14 hereof. This provision shall not limit in any way a claim for damages caused by your breach of this Agreement.

14. Governing Law; Arbitration; Jurisdiction/Venue; Waiver of Jury Trial. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania. Subject to the duty to arbitrate set forth below, any action to enforce or construe this Agreement shall exclusively be initiated in any federal or state court in the Commonwealth of Pennsylvania having jurisdiction over the subject matter, and you hereby consent to the personal jurisdiction of these courts. Subject to Aclaris' right to seek temporary, preliminary, and/or permanent injunctive relief for violations of Paragraphs 4 through 6 of this Agreement, any dispute or controversy arising under or in connection with this Agreement shall be resolved exclusively by binding arbitration in Pennsylvania in accordance with the Resolution of

Employment Dispute Rules of the American Arbitration Association before one arbitrator of exemplary qualifications and stature, who shall be selected in accordance with the procedures of the American Arbitration Association. The award of the arbitrator shall be final and binding and judgment upon the award may be entered in any court of competent jurisdiction as set forth above. All fees and expenses of the arbitrator and all other expenses of the arbitration, except for attorneys' fees, costs and witness expenses shall be paid by Aclaris. Each Party shall bear its own witness expenses, costs, and attorneys' fees. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HEREBY WAIVE THE RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT OR ANY DEALINGS BETWEEN THE PARTIES RELATING TO THE SUBJECT MATTER HEREOF.

15. Entire Agreement. This Agreement represents the entire agreement and understanding between the parties and supersedes all prior discussions, negotiations, representations, agreements, or general releases between the parties, either written or oral, regarding the subject hereof. Any other prior agreements between the parties are hereby terminated and shall have no other force or effect. Aclaris has made no promises to you and owes no payments or monies of any kind to you, other than those specified in this Agreement.

16. Modification. This Agreement may be amended only by written instrument designated as an amendment to this Agreement and executed by the parties hereto.

17. Remedies. All remedies at law or in equity shall be available for the enforcement of this Agreement. This Agreement may be pleaded as a full bar to the enforcement of any claim which you may have against Aclaris.

18. Severability. If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction or an arbitrator, that provision will be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with applicable law, and the remaining provisions of this Agreement will not be affected thereby.

19. Waiver. The failure of or delay by either party to enforce performance by the other party of any provision of this Agreement or to exercise any right under this Agreement will not be construed as a waiver of that party's right to assert or rely upon any provision of this Agreement or any such right in that or any other instance. Any waiver of any provision hereof shall be limited to the specific circumstances to which it applies and will not be construed as a waiver of any other provision hereof or of the same provision with respect to any other circumstances.

20. Assignment. You shall not assign this Agreement or any of your rights and/or obligations under this Agreement to any other person. The rights and protections of Aclaris hereunder shall extend to any successors or assigns of Aclaris and to its affiliates. Aclaris may, without your consent, assign this Agreement to any successor or assign.

21. Consultation with Attorney and Acceptance Period. You acknowledge that Aclaris has advised you to consult independent legal counsel of your choice before signing this Agreement, and that you have had the opportunity to consult such counsel and consider the terms of this Agreement for a period of twenty-one (21) days. You acknowledge that you understand all of the terms of this Agreement and their significance, that you knowingly and voluntarily assent to all of the terms and conditions contained herein, and that you are signing this Agreement voluntarily and of your own free will.

22. Revocation. This Agreement will not become effective until the eighth (8th) day following your signing this Agreement (the "Effective Date"), and you may revoke this Agreement at any time before the Effective Date. You acknowledge and understand that if you choose to revoke this Agreement after signing it, that to do so you must deliver or arrange to have delivered a written notice of revocation signed by you to Aclaris to the attention of Frank Ruffo, Chief Financial Officer, Aclaris Therapeutics, 640 Lee Road, Suite 200, Wayne, Pennsylvania 19087 no later than 5:00 p.m. Eastern Standard Time on the seventh (7th) day following the day you sign this Agreement. If the last day of the revocation

period falls on a weekend or holiday, the last day of the revocation period will be deemed to be the next business day. If you revoke this Agreement in this manner, the Agreement shall automatically be null and void.

23. Supplemental Release. In further consideration for the payment and benefits set forth in Paragraph 2 (a) (i), and (iii) –(v) and as a condition precedent to such payment and benefits, you shall execute the Supplemental Release of Claims (the "Supplemental Release") in the form attached hereto as Appendix A. The Supplemental Release may not be signed prior to the Retirement Date.

24. Notices. All notices must be in writing. Your notices to Aclaris must be addressed to Aclaris to the attention of Frank Ruffo, Chief Financial Officer, Aclaris Therapeutics, 640 Lee Road, Suite 200, Wayne, Pennsylvania 19087. Aclaris' notices to you will be mailed or delivered to your last home address which you have provided to Aclaris in writing.

25. Counterparts. This Agreement may be executed simultaneously in several counterparts and by facsimile, each of which shall be an original and all of which shall constitute but one and the same instrument. The parties agree that execution of this Agreement by industry standard electronic signature software and /or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

26. Disability and/or Death. In the event of your disability and/or death, you, your heirs, or your estate, as the case may be, shall be entitled to the payments and benefits set forth in this Agreement, which payments and benefits shall be paid in accordance with Paragraph 2.

. Signatures. The parties to this Agreement each acknowledge that the terms of this Agreement are contractual, that they are acting of their own free will, that they have had a sufficient opportunity to read and review the terms of this Agreement, that they are voluntarily entering into this Agreement with full knowledge of its respective provisions and effects, and that they have voluntarily caused the execution of this Agreement.

ACLARIS THERAPEUTICS, INC.

/s/ Kamil Ali-Jackson
Kamil Ali-Jackson

Date: 11/1/21

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

Date: November 1, 2021

Appendix A

SUPPLEMENTAL RELEASE OF CLAIMS

I, Kamil Ali-Jackson, hereby acknowledge and affirm that I executed a Severance Agreement and General Release with **Aclaris Therapeutics, Inc.** ("**Aclaris**"), dated November 1, 2021 (the "**Agreement**"). Pursuant to that Agreement, I am required to enter into this Supplemental Release of Claims ("**Supplemental Release**") with Aclaris, which extends the release of claims set forth in the Agreement, in order to receive the consideration set forth in Paragraph 2 of the Agreement. I, therefore, agree as follows:

1. An unexecuted copy of this Supplemental Release was attached to the Agreement. I hereby certify and acknowledge that I received this Supplemental Release at least twenty-one (21) days before I was required to sign it.

2. General Release.

   a) In consideration of the payment and benefits described in Paragraph 2 of the Agreement, I hereby generally release and discharge Aclaris from any and all suits, causes of action, complaints, charges, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown (hereinafter "claims"), which I ever had or now have against Aclaris arising out of or relating to any matter, thing or event occurring up to and including the date of this Supplemental Release. I also release Aclaris from any and all claims for wrongful discharge, defamation, unfair treatment, violation of public policy, breach of express or implied contract, intentional or negligent infliction of emotional distress, any and all tort claims or any other claim related to my employment with Aclaris or the termination of that employment for any and all reasons, up to and including the date of this Agreement. I specifically release Aclaris from any claim relating to or arising out of my employment with or termination of employment from Aclaris, including, but not limited to, any rights or claims I may have based upon Title VII of the Civil Rights Act of 1964, as amended, which prohibits discrimination in employment based on race, color, creed, religion, national origin or sex; the Age Discrimination in Employment Act, including the Older Workers Benefits Protection Act ("ADEA"), which prohibits discrimination on the basis of age; the Equal Pay Act, which prohibits paying men and women unequal pay for equal work; the Americans with Disabilities Act of 1990, as amended, which prohibits discrimination against disabled persons; the Family Medical Leave Act, as amended, which permits extended time away from work to handle certain family or medical needs; the Employee Retirement Income Security Act, which regulates employment benefits; the Pennsylvania Human Relations Act, which prohibits discrimination in employment based on race, color, religion, sex, disability, national origin, age, or the results of genetic testing; the Missouri Human Rights Act (MHRA); the Missouri Equal Pay for Women Act; the Missouri Service Letter Statute; the Missouri Minimum Wage Law; the Missouri Wage Payment Law; St. Louis City Ordinance No. 67119, as amended ;the False Claims Act, 31 U.S.C. § § 3729-3733 (including the qui tam provision thereof); the Consolidated Omnibus Budget Reconciliation Act of 1986; the Rehabilitation Act of 1973; the Electronic Communications Privacy Act of 1986 (including the Stored Communications Act); the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the Worker Adjustment and Retraining Notification Act of 1988, 29 U.S.C. § 210l, et seq.; and any and all other federal, state or local laws or regulations prohibiting employment discrimination or which otherwise regulate employment terms and conditions, except as such release is limited by applicable laws. This is a general release and covers claims that I know about presently and those that I may not know about up through the date of this Supplemental Release. This release specifically includes any and all claims for attorney's fees and costs which I incur for any reason arising out of or relating to any or all matters covered by this Supplemental Release.

b) I hereby represent and warrant that I have no knowledge of any acts or omissions by Aclaris or any other party released herein that are or could be construed as a breach or violation of the federal and state employment laws administered by the Equal Employment Opportunity Commission or any comparable state or local fair employment practices agencies, or of the National Labor Relations Act, 29 U.S.C. § 157, or of the False Claims Act, 31 U.S.C. § § 3729-3733, or of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Nothing in this Supplemental Release should be construed as prohibiting me from responding to inquiries from or otherwise reporting possible violations of federal or state law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation. However, by signing this Supplemental Release, I hereby waive and release any and all right to benefit personally or monetarily as a result of any such inquiry, complaint, or investigation. This paragraph applies to all claims I could have brought prior to the date of this Supplemental Release and is a material inducement of this Supplemental Release.

c) Notwithstanding the broad scope of the general release above in Paragraph 2(a), this Supplemental Release is not intended to bar any claims that, as a matter of law, whether by statute or otherwise, may not be waived, such as claims for workers' compensation benefits, unemployment insurance benefits and any challenge to the validity of my general release of claims under the ADEA as set forth in this Supplemental Release. Nothing in this Supplemental Release is intended to interfere with my right to file a charge or participate in an administrative investigation or proceeding; any claims by me (or on my behalf) for personal relief including, without limitation, reinstatement, or monetary damages, would be barred. I specifically understand that, in the event a complaint or charge is filed, I shall personally have no right to any relief whatsoever against Aclaris, including having no right to reinstatement, monetary damages or attorneys' fees.

3. I acknowledge that Aclaris has advised me to consult independent legal counsel of my choice before signing this Supplemental Release, and that I have had the opportunity to consult such counsel and consider the terms of this Supplemental Release for a period of twenty-one (21) days.

4. I acknowledge that this Supplemental Release will not become effective until the eighth (8th) day following my signing this Supplemental Release (the "Supplemental Release Effective Date"), and I may revoke this Supplemental Release at any time before the Supplemental Release Effective Date. I acknowledge and understand that if I choose to revoke this Supplemental Release after signing it, that to do so I must deliver or arrange to have delivered a written notice of revocation signed by me to Aclaris to the attention of Frank Ruffo, Chief Financial Officer, Aclaris Therapeutics, 640 Lee Road, Suite 200, Wayne, Pennsylvania 19087 no later than 5:00 p.m. Eastern Standard Time on the seventh (7th) day following the day I sign this Supplemental Release. If the last day of the revocation period falls on a weekend or holiday, the last day of the revocation period will be deemed to be the next business day. If I revoke this Supplemental Release in this manner, the Supplemental Release shall automatically be null and void and I understand that I will not be entitled to the payment and benefits described in Paragraph 2 of the Agreement.

5. I also make the following acknowledgements and representations:

a) I understand that rights or claims which may arise after the date this Supplemental Release is executed are not waived by me;
b) I have carefully read and fully understand all of the provisions of this Supplemental Release, I knowingly and voluntarily agree to all of the terms set forth in this Supplemental Release and I acknowledge that in entering into this Supplemental Release, I am not relying on any representation, promise or inducement made by Aclaris or its representatives with the exception of those promises contained in this Supplemental Release and the Agreement;

c) The consideration that I will receive in exchange for the Agreement and this Supplemental Release is something of value to which I am not already entitled.

d) I represent, as of the date of this Supplemental Release, I have not filed any lawsuits, charges, complaints, petitions, claims or other accusatory pleadings against Aclaris or any of the other released parties in any court, arbitral forum or with any governmental agency related to the matters released in this Supplemental Release.

e) I have returned all Aclaris property in accordance with Paragraph 5(a) of the Agreement.

f) I agree that this Supplemental Release is part of the Agreement.

Agreed to and Accepted:

KAMIL ALI-JACKSON

Signature: _____

Date: _____

January 7, 2022

David Gordon

RE: Severance Agreement and General Release

Dear David:

This letter is intended to set forth the terms of your separation from employment with Aclaris Therapeutics, Inc. and your general release and waiver of claims in favor of Aclaris Therapeutics, Inc., and its parents, subsidiaries, affiliates, and all related corporate entities and partnerships, and their current or former officers, directors, partners, shareholders, members, representatives, agents, employees, predecessors, successors and assigns ("Aclaris").

The terms of this Severance Agreement and General Release ("Agreement") are as follows, and you and Aclaris, intending to be legally bound and for good and valuable consideration, each agree to all of the following terms:

1. Your Termination from Employment. Your employment will be terminated effective January 7, 2022 (the "Termination Date"). Aclaris will pay all compensation due and owing to you as of the Termination Date, in accordance with its usual compensation and payroll practices.

2. Severance Pay and Benefits.

a. Severance Pay. Subject to the terms of this Agreement, you will be entitled to receive a severance payment in the amount of $169,781.20 constituting the total gross amount of your 2021 bonus ("Severance Payment"). The Severance Payment will be paid in one lump sum via direct deposit within thirty (30) days following the Termination Date in accordance with Aclaris' usual compensation and payroll practices. Aclaris will deduct all normal tax withholdings and deductions required by law. Your direct deposit statements will be sent to your home address via United States first class mail. The Severance Payment specified in this paragraph is the only severance payment to which you will be entitled.

b. Accrued and Unused Vacation Time. You will also be paid for accrued but unused vacation time that is owed under the terms of Aclaris' policies in one lump sum via direct deposit on the next regular payroll cycle following the Termination Date in accordance with Aclaris' usual compensation and payroll practices. Aclaris will deduct all normal tax withholdings and deductions required by law. Your direct deposit statements will be sent to your home address via United States first class mail.

c. Benefit Continuation. Aclaris will terminate your health, dental and vision coverages effective February 28, 2022. Aclaris will reimburse you for any premium that you pay to COBRA for the month of February. Thereafter, you may elect to continue your health, dental and vision coverages under COBRA for up to a balance of eighteen (18) months. In order to receive this COBRA benefit, you must complete and return the COBRA election

paperwork, which will be sent to your home approximately two (2) weeks after your loss of benefit coverage. Should you elect COBRA continuation, you will be fully responsible for payment of the premium cost of your COBRA coverage. All other benefits will be terminated effective as of the Termination Date. Your rights to any portability or conversion options with regard to your benefits will be mailed to your home in accordance with Aclaris' usual policies and/or practices. Continuation of coverage shall in all respects be subject to the requirements, conditions and limitations of COBRA and Aclaris' plans, which may be amended, modified or discontinued from time to time in the sole discretion of Aclaris.

d. Contingent Nature of Compensation. The Severance Payment under this Agreement shall not be paid unless you have signed and do not revoke this Agreement pursuant to Paragraphs 21 and 22 below, and provided that such payments will further be contingent upon your continued satisfaction of your covenants set forth in Paragraphs 4, 5 and 6 of this Agreement and your continued compliance with all of your legal duties and contractual obligations to Aclaris, including, without limitation, all obligations under this Agreement.

e. Savings Plan. You will be entitled to any vested amounts held by you or on your account in Aclaris' 401(k) savings plan, such amounts to be distributed to you or on your account in accordance with the plan terms and/or as required by applicable law.

f. No Other Compensation or Benefits. The compensation and benefits specified in Paragraph 1 and this Paragraph 2 are the only compensation and benefits to which you will be entitled, and no other compensation or benefits of any kind shall be provided to you. You acknowledge that you are not due or entitled to any salary, benefits or payments of any kind from Aclaris that are not specified in this Agreement.

3. Acknowledgment of Consideration. You acknowledge that, in return for executing this Agreement, particularly the general release in Paragraph 7, you are receiving satisfactory and adequate consideration to which you would not otherwise be entitled.

4. Transition and Cooperation.

a. Transition. You will fully cooperate with Aclaris to affect a professional, cooperative transition of your work and responsibilities.

b. Future Cooperation with Aclaris and its Counsel. You will, upon Aclaris' reasonable request, cooperate to the best of your ability with Aclaris and with any legal counsel, expert or consultant it may retain to assist it in connection with any judicial proceeding, arbitration, administrative proceeding, governmental investigation or inquiry, internal investigation or audit in which Aclaris is or becomes involved. This includes, but is not limited to, your assistance, cooperation and participation with respect to any matter in which you have information relevant to the inquiry, or in which you are identified as a witness. Your assistance, cooperation and participation include, without limitation, preparing for and attending depositions, assisting in answering factual questions for discovery, and preparing for and attending any hearing or trial as a witness. Aclaris agrees to reimburse you for any reasonable out of pocket expenses incurred as a result of your assistance, cooperation and participation. In addition, Aclaris will pay you a reasonable amount of compensation as agreed by the parties in good faith as compensation for the time and effort required in providing the requested assistance. You will promptly notify Aclaris if you are subpoenaed by any person or entity (including, but not limited to, any governmental agency) to give information or testimony that in any way relates to your employment with or representation of Aclaris. You will testify truthfully in all such matters or proceedings. Nothing in this Agreement is intended to be or may be construed in any way as being dependent upon or contingent on the content of your testimony.

5. Confidentiality. You agree to the following terms relating to confidentiality:

a. Confidentiality: Return of Property. You agree to return to Aclaris, on the Termination Date or such earlier date as Aclaris may request in its sole discretion, all company keys, cards, materials, laptop computers and other company property, including without limitation, all confidential and/or proprietary business, financial or technical information such as, without limitation, writings, documents, manuals, notebooks, reports, audio/video work, inventions, formulas, processes, technical know-how, machines, compositions, computer software, microfiche, accounting methods, business plans and information systems including such materials, information and data which are in machine readable form or otherwise and any information gained through discussions and/or meetings, etc. of Aclaris, if you have not done so already, and you further agree not to reveal any confidential and/or proprietary business, financial or technical information to any other person or entity or to use such information for your benefit or the benefit of anyone else, either during or subsequent to your employment with Aclaris, without the prior written approval of Aclaris.

b. Confidentiality: Non-Disclosure. You agree not to use, publish or otherwise disclose any secret or confidential information or data of Aclaris or any information or data of others, which Aclaris is obligated to maintain in confidence. However, you shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that: (1) is made (a) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and (b) solely for the purpose of reporting or investigating a suspected violation of law; (2) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal; or (3) is or becomes a matter of public record without any breach of the terms of this Agreement by you. Disclosures to attorneys, made under seal, or pursuant to court order are also protected in certain circumstances under 18 U.S.C. 1833.

c. Confidentiality of the Agreement. You agree to keep this Agreement and its terms strictly confidential and not disclose this information to any third party (including any past, present, or future employees of Aclaris) other than your accountant, legal representative, and immediate family who also agree to keep this matter strictly confidential, except as directed by court order. The terms of this Agreement may be disclosed in an arbitration to enforce the terms as provided in Paragraph 14 below.

6. a. Non-Disparagement. You agree that you will not make any public statement that would adversely affect Aclaris' business in any manner, at any time, even beyond the date after which you will receive no further compensation or benefits pursuant to this Agreement. You further agree that you will not directly or indirectly take any actions, make any statements, or cause others to take any actions or make any statements that disparage, criticize, or reflect negatively on Aclaris or its actions, its products, services, or operations, or any of Aclaris' past, present, or future directors, officers, employees, agents or representatives, or any of their actions or decisions, or Aclaris' customers. Notwithstanding the foregoing, nothing in this paragraph is intended to restrict or impede you from providing testimony as required by law, from exercising legal rights to communicate with any government agency or from engaging in activities permitted under Section 7 of the National Labor Relations Act.

b. No Publicity. You agree that you will not, directly or indirectly, either personally or through others, issue or cause to be issued any oral or written or other form of public statements, publications, books, press releases, comments or other narrative, regardless of their form (print, oral, visual, recorded, electronic or otherwise), including without limitation any communication, interviews and/or statements to any member of the media (including without limitation any print, broadcast or electronic media), concerning, referring or relating to, or which could fairly be understood to concern, refer or relate to, directly or indirectly, Aclaris or any of Aclaris' parents, subsidiaries, affiliates, directors, officers, employees, agents or representatives.

7. General Release.

a. Except as noted below in Paragraph 12, you hereby generally release and discharge Aclaris from any and all suits, causes of action, complaints, charges, obligations, demands, or claims of any kind, whether in law or in equity, direct or indirect, known or unknown (hereinafter "claims"), which you ever had or now have against Aclaris arising out of or relating to any matter, thing or event occurring up to and including the date of this Agreement. You also release Aclaris from any and all claims for wrongful discharge, defamation, unfair treatment, violation of public policy, breach of express or implied contract, intentional or negligent infliction of emotional distress, any and all tort claims or any other claim related to your employment with Aclaris or the termination of that employment for any and all reasons, up to and including the date of this Agreement. You specifically release Aclaris from any claim relating to or arising out of your employment with or termination of employment from Aclaris, including, but not limited to, any rights or claims you may have based upon Title VII of the Civil Rights Act of 1964, as amended, which prohibits discrimination in employment based on race, color, creed, religion, national origin or sex; the Age Discrimination in Employment Act including the Older Workers Benefits Protection Act ("ADEA"), which prohibits discrimination on the basis of age; the Equal Pay Act, which prohibits paying men and women unequal pay for equal work; the Americans with Disabilities Act of 1990, as amended, which prohibits discrimination against disabled persons; the Family Medical Leave Act, as amended, which permits extended time away from work to handle certain family or medical needs; the Employee Retirement Income Security Act, which regulates employment benefits; the Pennsylvania Human Relations Act, which prohibits discrimination in employment based on race, color, religion, sex, disability, national origin, age, or the results of genetic testing; the False Claims Act, 31 U.S.C. § § 3729-3733 (including the qui tam provision thereof); the Consolidated Omnibus Budget Reconciliation Act of 1986; the Rehabilitation Act of 1973; the Electronic Communications Privacy Act of 1986 (including the Stored Communications Act); the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b); the Worker Adjustment and Retraining Notification Act of 1988, 29 U.S.C. § 210l, et seq.; and any and all other federal, state or local laws or regulations prohibiting employment discrimination or which otherwise regulate employment terms and conditions, except as such release is limited by applicable laws. This is a general release and covers claims that you know about presently and those that you may not know about up through the date of this Agreement. This release specifically includes any and all claims for attorney's fees and costs which you incur for any reason arising out of or relating to any or all matters covered by this Agreement.

b. You hereby represent and warrant that you have no knowledge of any acts or omissions by Aclaris or any other party released herein that are or could be construed as a breach or violation of the federal and state employment laws administered by the Equal Employment Opportunity Commission or any comparable state or local fair employment practices agencies, or of the National Labor Relations Act, 29 U.S.C. § 157, or of the False Claims Act, 31 U.S.C. § § 3729-3733, or of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b). Nothing in this Agreement should be construed as prohibiting you from responding to inquiries from or otherwise reporting possible violations of federal or state law or regulation to any governmental agency or entity, including but not limited to the Department of Justice, the Securities and Exchange Commission, Congress, and any agency Inspector General, or making other disclosures that are protected under the whistleblower provisions of federal or state law or regulation. However, by signing this Agreement you hereby waive and release any and all right to benefit personally or monetarily as a result of any such inquiry, complaint, or investigation. This paragraph applies to all claims you could have brought prior to the date of this Agreement and is a material inducement of this Agreement.

8. No Admission. This Agreement represents a full, complete and binding compromise of claims and shall not be construed as an admission by any party of any liability or of any contention or allegation made by the other party.

9. References. In accordance with Aclaris' usual policies, when responding to requests related to your future employment or references for you, Aclaris will provide only information regarding your employment start date, Termination Date and job titles. Any such requests should be directed to Spencer Brown, Vice President, Legal Affairs.

10. Employment Termination Acknowledgment. You confirm that your employment with Aclaris terminates effective on the Termination Date, and that Aclaris has settled all obligations to you (except with respect to Aclaris' obligations under this Agreement). You agree to waive any claim to future employment with Aclaris. You further agree that you will not, at any time in the future, apply for or seek any type of employment or independent contractor work with Aclaris, including but not limited to full-time, part-time, or temporary employment or any other form of contract work. If you do so, you hereby acknowledge that Aclaris' refusal to hire you or subsequent termination of your employment or contract, will be legitimately based upon this provision and not for some other, unlawful reason.

11. No Pending Claims. You acknowledge that you have not filed a lawsuit in any federal or state court or initiated any other governmental, administrative, or regulatory proceeding or investigation against Aclaris, and that you have not assigned any claim against Aclaris to any other person or entity.

12. Promise Not to Sue. You promise never to file any claim, complaint, demand for arbitration, or lawsuit against Aclaris or allow any other party acting on your behalf to do so based on or asserting any claims relating to your employment with Aclaris, your termination of employment with Aclaris, or any of the claims released herein. Notwithstanding the broad scope of the general release above in Paragraph 7, this Agreement is not intended to bar any claims that, as a matter of law, whether by statute or otherwise, may not be waived, such as claims for workers' compensation benefits, unemployment insurance benefits and any challenge to the validity of your general release of claims under the ADEA as set forth in this Agreement and Release. Nothing in this Agreement is intended to interfere with your right to file a charge or participate in an administrative investigation or proceeding; any claims by you (or on your behalf) for personal relief including, without limitation, reinstatement or monetary damages, would be barred. You specifically understand that, in the event a complaint or charge is filed, you shall personally have no right to any relief whatsoever against Aclaris, including having no right to reinstatement, monetary damages or attorneys' fees.

13. Forfeiture. If you breach this Agreement, including but not limited to the provisions of Paragraphs 4 through 6 hereof, the compensation contained in Paragraphs 1 and 2 of this Agreement shall be forfeited and Aclaris shall have no obligation to pay any amount other than your final salary as of the Termination Date and any other amounts that may be required by law to be paid. In addition, if you breach this Agreement after payment hereunder has been made, Aclaris shall be entitled to have the payment refunded pursuant to an adjudication under Paragraph 14 hereof. This provision shall not limit in any way a claim for damages caused by your breach of this Agreement.

14. Governing Law; Arbitration; Jurisdiction/Venue; Waiver of Jury Trial. This Agreement shall be governed by and construed in accordance with the laws of the Commonwealth of Pennsylvania. Subject to the duty to arbitrate set forth below, any action to enforce or construe this Agreement shall exclusively be initiated in any federal or state court in the Commonwealth of Pennsylvania having jurisdiction over the subject matter, and you hereby consent to the personal jurisdiction of these courts. Subject to Aclaris' right to seek temporary, preliminary, and/or permanent injunctive relief for violations of Paragraphs 4 through 6 of this Agreement, any dispute or controversy arising under or in connection with this Agreement shall be resolved exclusively by binding arbitration in Pennsylvania in accordance

with the Resolution of Employment Dispute Rules of the American Arbitration Association before one arbitrator of exemplary qualifications and stature, who shall be selected in accordance with the procedures of the American Arbitration Association. The award of the arbitrator shall be final and binding and judgment upon the award may be entered in any court of competent jurisdiction as set forth above. All fees and expenses of the arbitrator and all other expenses of the arbitration, except for attorneys' fees, costs and witness expenses shall be paid by Aclaris. Each Party shall bear its own witness expenses, costs, and attorneys' fees. TO THE FULLEST EXTENT PERMITTED BY LAW, THE PARTIES HEREBY WAIVE THE RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT OR ANY DEALINGS BETWEEN THE PARTIES RELATING TO THE SUBJECT MATTER HEREOF. YOU FURTHER AGREE THAT ANY CLAIMS MUST BE ARBITRATED SOLELY ON AN INDIVIDUAL, NON-CLASS AND NON-COLLECTIVE BASIS, AND UNDER NO CIRCUMSTANCE MAY ANY CLAIMS BE CONSOLIDATED WITH ANY ARBITRATION, ACTION OR LEGAL PROCEEDING INSTITUTED BY A THIRD PARTY FOR ANY PURPOSE. This provision, including the foregoing requirement that claims be asserted on an individual and not class basis, shall be interpreted in accordance with and subject to the Federal Arbitration Act ("FAA"), and all questions of arbitrability shall be referred to the arbitrator, to be determined in accordance with the AAA rules referenced above, and not any Court.

15. Entire Agreement. This Agreement represents the entire agreement and understanding between the parties and supersedes all prior discussions, negotiations, representations, agreements or general releases between the parties, either written or oral, regarding the subject hereof. Any other prior agreements between the parties are hereby terminated and shall have no other force or effect. Aclaris has made no promises to you and owes no payments or monies of any kind to you, other than those specified in this Agreement.

16. Modification. This Agreement may be amended only by written instrument designated as an amendment to this Agreement and executed by the parties hereto.

17. Remedies. All remedies at law or in equity shall be available for the enforcement of this Agreement. This Agreement may be pleaded as a full bar to the enforcement of any claim which you may have against Aclaris.

18. Severability. If any provision of this Agreement is held to be invalid or unenforceable by a court of competent jurisdiction or an arbitrator, that provision will be deemed to be restated to reflect as nearly as possible the original intentions of the parties in accordance with applicable law, and the remaining provisions of this Agreement will not be affected thereby.

19. Waiver. The failure of or delay by either party to enforce performance by the other party of any provision of this Agreement or to exercise any right under this Agreement will not be construed as a waiver of that party's right to assert or rely upon any provision of this Agreement or any such right in that or any other instance. Any waiver of any provision hereof shall be limited to the specific circumstances to which it applies and will not be construed as a waiver of any other provision hereof or of the same provision with respect to any other circumstances.

20. Assignment. You shall not assign this Agreement or any of your rights and/or obligations under this Agreement to any other person. The rights and protections of Aclaris hereunder shall extend to any successors or assigns of Aclaris and to its affiliates. Aclaris may, without your consent, assign this Agreement to any successor or assign.

21. Consultation with Attorney and Acceptance Period. You acknowledge that Aclaris has advised you to consult independent legal counsel of your choice before signing this Agreement, and that you have had the opportunity to consult such counsel and consider the terms of this Agreement for a period of forty-five (45) days. You

acknowledge that you understand all of the terms of this Agreement and their significance, that you knowingly and voluntarily assent to all of the terms and conditions contained herein, and that you are signing this Agreement voluntarily and of your own free will.

22. Revocation. This Agreement will not become effective until the eighth (8th) day following your signing this Agreement (the "Effective Date"), and you may revoke this Agreement at any time before the Effective Date. You acknowledge and understand that if you choose to revoke this Agreement after signing it, that to do so you must deliver or arrange to have delivered a written notice of revocation signed by you to Aclaris to the attention of Kamil Ali-Jackson, Chief Legal Officer, Aclaris Therapeutics, 640 Lee Road, Suite 200, Wayne, Pennsylvania 19087 no later than 5:00 p.m. Eastern Standard Time on the seventh (7th) day following the day you sign this Agreement. If the last day of the revocation period falls on a weekend or holiday, the last day of the revocation period will be deemed to be the next business day. If you revoke this Agreement in this manner, the Agreement shall automatically be null and void.

23. Notices. All notices must be in writing. Your notices to Aclaris must be addressed to Aclaris to the attention of Legal Department, Aclaris Therapeutics, Inc., 640 Lee Road, Suite 200, Wayne, Pennsylvania 19087. Aclaris' notices to you will be mailed or delivered to your last home address which you have provided to Aclaris in writing.

24. Counterparts. This Agreement may be executed simultaneously in several counterparts and by facsimile, each of which shall be an original and all of which shall constitute but one and the same instrument. The parties agree that execution of this Agreement by industry standard electronic signature software and /or by exchanging PDF signatures shall have the same legal force and effect as the exchange of original signatures, and that in any proceeding arising under or relating to this Agreement, each party hereby waives any right to raise any defense or waiver based upon execution of this Agreement by means of such electronic signatures or maintenance of the executed agreement electronically.

25. Signatures. The parties to this Agreement each acknowledge that the terms of this Agreement are contractual, that they are acting of their own free will, that they have had a sufficient opportunity to read and review the terms of this Agreement, that they are voluntarily entering into this Agreement with full knowledge of its respective provisions and effects, and that they have voluntarily caused the execution of this Agreement.

ACLARIS THERAPEUTICS, INC.

/s/ David Gordon	By: /s/ Neal Walker
David Gordon	Neal Walker
	President and Chief Executive Officer
Date: 01/06/2022	Date: 1/11/2022

ACLARIS THERAPEUTICS, INC.

SEVENTH 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 Seventh Amended & Restated Non-Employee Director Compensation Policy (this "***Policy***") for his or her Board service effective as of February 8, 2022 (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
    d. Member of the Research and Development Committee: $6,000

3. Annual Committee Chair Service Retainer (in addition to Committee Member Service Retainer):

    a. Chair of the Audit Committee: $12,500
    b. Chair of the Compensation Committee: $8,000
    c. Chair of the Nominating and Corporate Governance Committee: $4,500
    d. Chair of the Research and Development Committee: $8,000

4. Annual Chair 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 have 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 awards (the "***Initial Award***") with an aggregate grant date fair value (as calculated for financial reporting purposes) equal to the lesser of $320,000 and the grant date fair value of 22,500

stock options, 70% of which shall be granted as a stock option to purchase shares of the Company's Common Stock and 30% of which shall be granted as restricted stock units. 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 (as defined in the Plan) through such vesting dates.

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 awards (the "***Annual Award***") with an aggregate grant date fair value (as calculated for financial reporting purposes) equal to the lesser of $320,000 and the grant date fair value of 22,500 stock options, 70% of which shall be granted as a stock option to purchase shares of the Company's Common Stock and 30% of which shall be granted as restricted stock units; provided that in no event shall the aggregate grant date fair value of an Annual Award together with an Initial Award in a fiscal year exceed $320,000 for any Eligible Director. 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 dates.

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 (Nos. 333-212095 and 333-256337) and Form S-8 (Nos. 333-255922, 333-238079, 333-230614, 333-223922, 333-220149, 333-216703, 333-210379 and 333-207434) of Aclaris Therapeutics, Inc. of our report dated February 24, 2022 relating to the financial statements and the effectiveness of internal control over financial reporting, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP

Philadelphia, Pennsylvania
February 24, 2022

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 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 24, 2022

/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 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 24, 2022

/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, 2021 (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 24th day of February 2022.

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

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