



2024

Annual Report



EMPOWERING PATIENTS THROUGH
**THERAPEUTIC
INNOVATION**

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, 2024

Commission file number 001-37581

ACLARIS THERAPEUTICS, INC.

Incorporated under the Laws of the
State of Delaware

I.R.S. Employer Identification No.
46-0571712

701 Lee Road, Suite 103
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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant’s executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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

As of June 28, 2024, 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 \$76.1 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, 2025, 107,918,821 shares of common stock, \$0.00001 par value, were outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (this “Annual Report”) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), and Section 21E of the Securities Exchange Act of 1934, as amended (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 product candidates;
- the clinical utility of our product candidates;
- our plans and expectations related to manufacturing capabilities and strategy;
- our expectations regarding coverage and reimbursement of our product candidates, if approved;
- 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 product candidates, and earn revenue from such arrangements;
- our expectations regarding competition;
- our expectations regarding our continued reliance on third parties;
- the impacts of macroeconomic conditions 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 and RHOFADÉ, 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 small and large molecule product candidates for immuno-inflammatory diseases. Our proprietary KINect drug discovery platform combined with our preclinical development capabilities allows us to identify and advance potential product candidates that we may develop independently or in collaboration with third parties. In addition to identifying and developing our novel product 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 product candidates. We also provide contract research services to third parties enabled by our early-stage research and development expertise.

Our Approach

We are dedicated to developing a pipeline of novel product candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. Our approach to achieve this goal includes the following key elements:

- **Research and development expertise.** Our team of scientists and professionals has extensive experience in cell and molecular biology, biochemistry, enzymology, biomarker development, immunology, in vivo efficacy models, structure-based drug design (“SBDD”), and medicinal chemistry. In addition, our team has broad experience in clinical development and strategy across atopic, respiratory and immunologic diseases.
- **Develop innovative biologic product candidates targeting validated pathways.** We are advancing biologics programs focused on well-characterized pathways in immuno-inflammatory diseases. Our approach leverages established biological targets while incorporating novel mechanisms and dual-targeting strategies to potentially enhance therapeutic outcomes. The biologics market has grown significantly, with monoclonal antibodies representing a major segment of U.S. Food and Drug Administration (“FDA”) approved therapeutics. Our biologics pipeline includes bosakitug (ATI-045), an anti-thymic stromal lymphopoietin (“TSLP”) monoclonal antibody which has unique differentiation demonstrated by its slow dissociation rate, high residence time and high potency. TSLP is a key mediator in various inflammatory conditions, making it an attractive therapeutic target. We are also advancing ATI-052, a novel bispecific antibody that simultaneously targets both TSLP and interleukin-4 receptor (“IL4R”), potentially offering enhanced efficacy through dual pathway inhibition. By pursuing both traditional monoclonal antibodies and innovative bispecific approaches, we aim to develop differentiated biological therapies that address significant unmet needs in immuno-inflammatory diseases.
- **Create small molecule medicines through kinome innovation.** We are exploring the kinome, a subset of the human genome that consists of a collection of 518 protein kinases, one of the largest of all human gene families, responsible for signal transduction controlling cellular responses. Classified into eight major groups based on their structural similarity to each other, kinases are key regulators of cell function in many cell processes. By transferring phosphates to other molecules, kinases can induce a cellular response to environmental cues. Dysregulation and/or activating/blocking mutations in kinases can disrupt normal cell signaling and lead to diseases ranging from autoimmune diseases to diabetes and cancer, making them important targets for drug development. There are over 80 kinase inhibitors approved by the FDA on the market; however, these drugs only target a small fraction of the kinome, with many clinically relevant kinase targets lacking validated inhibitors. In 2023, the kinase inhibitors market was valued at over \$57 billion. We’re focused on novel approaches toward the design and development of kinase inhibitors that target key enzymes involved in chronic inflammation, autoimmune disease, and the regulation of cancer growth, survival and metastasis. We are developing ATI-2138, a highly potent, oral small molecule covalent IL2-inducible tyrosine kinase (“ITK”) and Janus kinase (“JAK”) 3 inhibitor for autoimmune diseases. In addition, we are also progressing to candidate selection a second generation ITK selective inhibitor designed to eliminate crossover on JAK3.
- **Identify additional product candidates through our KINect drug discovery platform.** Our proprietary KINect platform enables us to identify potential small molecule product candidates through a unique combination of our proprietary chemical library of kinase inhibitors, our novel approach to inhibitor modalities, our expertise in SBDD and our custom kinase assays.

- **Broaden our drug development pipeline internally and externally.** A key element of our strategy is to build and expand our pipeline of product candidates. To build our pipeline, we may seek to in-license or acquire additional product candidates, in addition to developing assets in-house.
- **Pursue strategic alternatives for our product 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 product candidates.

Our Key Product Candidate Pipeline

Our pipeline of key product candidates is summarized in the table below.

		PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	PARTNER
Bosakitug (ATI-045) TSLP mAb Subcutaneous	Severe Asthma					CTTQ (China)*
	Chronic Rhinosinusitis with Nasal Polyps					CTTQ (China)*
	Atopic Dermatitis (moderate-to-severe)					
	Chronic Obstructive Pulmonary Disease					CTTQ (China)*
ATI-2138 ITK/JAK3 Inhibitor Oral	Atopic Dermatitis (moderate-to-severe)					
ATI-052 TSLP x IL4R BsAb Subcutaneous	Respiratory/ Dermatology					
Undisclosed ITK Selective Inhibitor Oral	Autoimmune					

* This trial is sponsored and conducted by Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (“CTTQ”) or its affiliates.

Bosakitug, an Investigational, Novel Anti-TSLP Monoclonal Antibody

Bosakitug (ATI-045) is an investigational, novel, humanized anti-TSLP monoclonal antibody that specifically binds to human TSLP with high affinity and long residence time, blocking its interaction with the receptor complex and disrupting signal transduction. This mechanism prevents a broad range of immune cells targeted by TSLP from releasing proinflammatory cytokines. Bosakitug has the potential to treat a variety of atopic, immunologic and respiratory diseases. We exclusively license global rights (excluding Greater China) to bosakitug from Biosion, Inc. (“Biosion”).

In a Phase 2a, single-arm, proof-of-concept trial in 22 U.S. patients with moderate to severe atopic dermatitis conducted by Biosion, bosakitug demonstrated a positive pharmacodynamic, safety and efficacy profile, with 94% of patients achieving a 75% improvement in the Eczema Area and Severity Index (“EASI”), 65% of patients achieving EASI-90, and 88% of patients achieving an Investigator’s Global Assessment (“IGA”) score of 0 or 1 (clear or almost clear skin), at week 26 (n=17). Bosakitug was generally well-tolerated with no serious adverse events reported. The most common treatment-emergent adverse event was headache (22.7% of patients). Grade 1 injection site reactions, primarily tenderness, occurred in 47.6% of patients.

We plan to initiate a Phase 2b trial of bosakitug in patients with moderate to severe atopic dermatitis in the first half of 2025.

Bosakitug is also currently being evaluated in multiple Phase 2 trials in severe asthma, chronic rhinosinusitis with nasal polyps (“CRSwNP”) and moderate to severe chronic obstructive pulmonary disease (“COPD”) in China by CTTQ. CTTQ licenses bosakitug from Biosion in Greater China. We anticipate data from the severe asthma trial and CRSwNP trial in the first half of 2025, which we expect will inform our internal development programs.

ATI-2138, an Investigational Oral Covalent ITK/JAK3 Inhibitor

ATI-2138 is an investigational oral covalent inhibitor of ITK and JAK3 for the potential treatment of T cell-mediated autoimmune diseases. The ITK/JAK3 compound interrupts T cell signaling through the combined inhibition of ITK/JAK3 pathways in lymphocytes.

In September 2023, we announced positive results from our two-week Phase 1 placebo-controlled, randomized, multiple ascending dose (“MAD”) trial of ATI-2138. The trial was designed to investigate the safety, tolerability, pharmacokinetics (“PK”) and pharmacodynamics (“PD”) of ATI-2138 in healthy volunteers. The trial enrolled 60 healthy volunteers across 6 dosing cohorts ranging from 10 to 80 mg of total daily doses, with eight volunteers receiving ATI-2138 and two volunteers receiving placebo in each arm. Data from the trial demonstrated that ATI-2138 was generally well tolerated at all doses tested and had dose proportional PK. Additionally, ATI-2138 demonstrated a dose-dependent inhibition of both ITK and JAK3 exploratory PD biomarkers, with near maximal inhibition achieved at the 30 mg total daily dose. No serious adverse events were reported.

We are conducting a Phase 2a open-label trial to investigate the safety, tolerability, PK, efficacy, and PD of ATI-2138 administered over 12 weeks in approximately 15 patients in the United States with moderate to severe atopic dermatitis. The primary endpoints are safety related parameters. Secondary endpoints include EASI response (EASI-50, EASI-75, EASI-90), validated IGA response, body surface area response and other pertinent efficacy related measures. We expect to announce top-line data in the first half of 2025.

We are also exploring the potential of ATI-2138 in additional indications that are relevant to the mechanism of action, including alopecia areata and vitiligo.

ATI-052, an Investigational, Novel Anti-TSLP and Anti-IL4R Bispecific Antibody

ATI-052 is a humanized anti-TSLP and anti-IL4R bispecific antibody that blocks both the upstream TSLP receptor signal transduction and downstream IL4R activation thereby inhibiting this central proinflammatory pathway. ATI-052 utilizes the same TSLP as bosakitug but is engineered to bind more tightly to the neonatal Fc receptor (“FcRn”), potentially extending its half-life. ATI-052 has the potential to treat a variety of atopic, immunologic and respiratory diseases.

We plan to submit an Investigational New Drug (“IND”) application for ATI-052 in the first quarter of 2025. If the IND is allowed, we plan to initiate a Phase 1 single ascending dose and MAD trial of ATI-052.

Other Investigational Product Candidates

Lepzacinib, an Investigational Topical “Soft” JAK 1/3 Inhibitor

Lepzacinib (ATI-1777) is an investigational topical “soft” JAK 1/3 inhibitor for the potential treatment of atopic dermatitis and potentially other dermatologic conditions. “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 January 2024, we announced positive top-line results from our Phase 2b multicenter, randomized, double-blind, vehicle-controlled, parallel-group trial of lepzacinib in patients with mild to severe atopic dermatitis. The trial was designed to evaluate the efficacy, safety, tolerability and PK of multiple concentrations (0.5%, 1% and 2%) of twice daily (“BID”) treatment with lepzacinib and a single concentration (2%) of once daily (“QD”) treatment with lepzacinib. The trial randomized 250 patients with mild, moderate or severe atopic dermatitis, including adults and children as young as 12 years old, across 30 clinical trial sites in the United States. The trial met the primary efficacy endpoint, the percent

change from baseline in EASI score at week 4, with statistical significance for patients treated with lepzacitinib 2% BID compared to patients treated with vehicle (69.7% versus 58.7% in the pooled vehicle group, $p=0.035$). In addition, a PK analysis showed minimal levels of exposure to lepzacitinib. The mean steady state trough drug levels at week 4 were 0.319 ng/mL, representing 0.7% of IC₅₀ for JAK 1/3 inhibition in whole blood. In total, 97% of lepzacitinib plasma samples from dosed patients had concentrations below 1/10th of the IC₅₀, and six samples (from five lepzacitinib treated patients) of 764 samples analyzed had concentrations above 1/4 of the IC₅₀. No meaningful safety findings were observed and lepzacitinib was well tolerated.

We are currently seeking a global development and commercialization partner for this program (excluding Greater China). In 2022, we granted Pediatrix Therapeutics, Inc. exclusive rights to develop and commercialize lepzacitinib in Greater China.

Zunsemetinib, an Investigational Oral MK2 Inhibitor

Zunsemetinib (ATI-450) is an investigational oral, novel, small molecule selective inhibitor of the mitogen-activated protein kinase-activated protein kinase 2 (“MK2”) signaling pathway for the potential treatment of metastatic breast cancer (“MBC”) and pancreatic ductal adenocarcinoma (“PDAC”).

MBC: Phosphorylated MK2 is upregulated in primary tumors and metastatic bone lesions from MBC patients. MK2 is responsible for the production of a subset of critical pro-tumorigenic factors secreted by the stromal microenvironment to support tumor growth and metastasis. Additionally, MK2 drives both metastatic and chemotherapy induced bone loss in MBC patients through, at least in part, its role in RANKL biology and osteoclast production and activation. In preclinical studies, zunsemetinib has been demonstrated to impact murine models of MBC through inhibition of tumor growth and metastasis along with bone preservation.

PDAC: Phosphorylated MK2 is highly expressed in PDAC tissue and expression levels are directly associated with poor outcomes in patients with PDAC. The current first and second line standard of care for PDAC patients is FOLFIRINOX combination chemotherapy. Irinotecan and its metabolite, SN-38, are the main drivers of cancer cell apoptosis associated with FOLFIRINOX. The effectiveness of FOLFIRINOX is limited by pro-survival resistance mechanisms that are driven through SN-38 activation of the MK2 pathway and phosphorylation of two direct MK2 substrates, HSP-27 and Beclin-1. In both patient derived xenografts and in the autochthonous genetic KPPC model of PDAC in mice, zunsemetinib has demonstrated that it blocks phosphorylation and activation of HSP-27, induces tumor cell killing and enhances the efficacy of FOLFIRINOX (a version of FOLFIRINOX used in murine models).

We plan to support Washington University in St. Louis in its investigator-initiated Phase 1b/2 trials of zunsemetinib in patients with MBC and PDAC.

Discovery Programs and KINect Drug Discovery Platform

We conduct small molecule drug discovery and preclinical development research through KINect, our proprietary drug discovery platform, which we acquired as part of our acquisition of Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) (“Confluence”), in 2017. Our KINect platform enables us to identify potential small molecule product candidates through a unique combination of our proprietary chemical library of kinase inhibitors, our novel approaches to inhibitor modalities, our expertise in SBDD, and our custom kinase assays.

Our focus has been on difficult to drug kinase targets that exhibit some level of clinical, genetic and/or pharmacological disease validation. Our approach involves the following mechanisms: (1) reversible and irreversible covalent inhibitors, (2) molecular glue/complex targeted inhibitors and (3) targeted protein degraders. These novel approaches are currently being utilized to prosecute additional validated, difficult to drug kinase targets with the goal of demonstrating potential platform utility.

Reversible and Irreversible Covalent Inhibitors: Central to the KINect platform is our novel chemical library of several hundred compounds specifically designed to target non-catalytic cysteine residues near the adenosine triphosphate (“ATP”) binding site of more than 300 kinases. Furthermore, using state-of-the-art drug modeling software, we are able to elaborate the structure of viable drug-like compounds culled from our library and extensive in silico libraries to optimize reversible binding to the target kinase and allow them to selectively form a covalent bond with the cysteine residue near the ATP site on the specific kinase target. This approach delivers inhibitors exhibiting enhanced potency, selectivity and

biochemical efficiency thereby allowing pharmacological access to ‘hard to drug’ kinases. We then assess the function of the newly created compounds with physiologically relevant custom assays that effectively translate to human diseases.

Molecular Glue/Complex Targeted Inhibitors: In cells, protein kinases function in the context of multicomponent signalosome complexes. Targeting kinase complexes with small molecule drugs designed to either stabilize (molecular glue) and/or generate inactive complexes provides several potential advantages over those designed against a single protein target including: (1) utilizing a more physiological translatable complex as the target, (2) providing novel protein interfaces devoid of competing endogenous ligands to target, and (3) identifying new chemical matter and modalities for difficult to drug kinase targets. As such, we have identified target complexes of interest and have initiated discovery programs against these targets.

Targeted Protein Degraders: We believe targeted protein degraders represent a powerful approach to develop drugs against biologically important but difficult to drug proteins including kinases. This approach harnesses cellular protein clearing machinery to selectively remove proteins from the cell in contrast to inhibiting their function. This approach is particularly useful for kinases that have both catalytic and scaffolding functions for which inhibitors will only partially impact biology. We are exploring selective degraders of kinase targets with multiple biological functions in addition to the catalytic activity.

This integrated drug discovery engine allows us to rapidly progress potential product candidates from idea to IND. We believe this platform can generate inhibitors with fit-for purpose mechanisms ranging from reversible, to reversible-covalent to irreversible-covalent kinase and kinase complex inhibitors along with targeted protein degraders.

We are actively progressing several discovery programs focused on delivering the next wave of small molecule product candidates from our KINect platform. Our discovery efforts center on targeting kinases that play pivotal roles in various inflammatory, autoimmune, and oncology pathways.

In addition to our small molecule discovery efforts, we maintain capabilities in biologics discovery to complement our therapeutic portfolio. Through our integrated discovery platform, we can progress biologics candidates from concept through lead optimization, employing robust screening cascades and protein characterization techniques to identify molecules with desired therapeutic properties. This complementary approach to our small molecule programs enables us to pursue optimal therapeutic modalities for each target and indication of interest.

We intend to evaluate both internal and external development options, including strategic partnerships, for these assets.

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

With respect to bosakitug, we are aware of a number of companies with monoclonal antibodies also targeting the TSLP ligand, and one company targeting the TSLP receptor, including Amgen and AstraZeneca (tezepelumab), KeyMed Biosciences (CM-326), Uniquity Bio (solrikritug), Windward Bio (WIN378), Tavotek Biotherapeutics (TAVO101), GlaxoSmithKline (“GSK”) (GSK5784283), and UpStream Bio (verekutig). As a potential treatment for atopic dermatitis, there are several different types of therapies in the atopic dermatitis market, such as biologics, oral and topical corticosteroids, oral and topical calcineurin inhibitors, oral mycophenolate products, JAK inhibitors, other oral antibiotics and antihistamines and phototherapy. There are also several prescription, non-prescription and over-the-counter 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 (upadacitinib), Incyte (ruxolitinib), LEO Pharma A/S (delgocitinib), Pfizer (crisaborole; abrocitinib), Eli Lilly (lebrikizumab), Dermavant Sciences (tapinarof), and Regeneron Pharmaceuticals and Sanofi (dupilumab). In addition, we are aware of a number of companies, including large pharmaceutical companies, such as Amgen (rocatinlimab), Eli Lilly (ucenprubart), LEO Pharma A/S (tralokinumab), Pfizer (PF-07264660; PF-07275315), KeyMed Biosciences (stapokibart), and Tavotek Biotherapeutics (TAVO101) developing and conducting clinical trials for investigational product candidates that could compete with bosakitug in each case if approved, for the treatment of atopic dermatitis. With respect to bosakitug as a potential treatment for asthma, existing therapeutics for asthma include controller medications, reliever medications and more recently, biologics from Genentech and Novartis (omalizumab), Sanofi and Regeneron (dupilumab), GSK (mepolizumab), and AstraZeneca (benralizumab), with other products in development, including by UpStream Bio (verekutig), Amgen and AstraZeneca (tezepelumab), KeyMed Biosciences (CM-326), Uniquity Bio (solrikutug), Sanofi (rilzabrutinib), GSK (GSK5784283), and Windward Bio (WIN378). Existing therapeutics for CRSwNP include topical corticosteroids, nasal saline irrigations and more recently, biologics from Genentech and Novartis (omalizumab), Sanofi and Regeneron (dupilumab), and GSK (mepolizumab). Companies such as GSK, KeyMed Biosciences, and Upstream Bio are also developing potential therapeutics for CRSwNP. Existing therapeutics for COPD include inhaled steroids, bronchodilator inhalers, and recently, a biologic by Sanofi and Regeneron (dupilumab). Amgen and AstraZeneca (tezepelumab) are also conducting clinical trials in COPD.

With respect to ATI-2138, there are several companies that are developing or have approved drugs that target either ITK or JAK that could compete with ATI-2138, if approved. For example, Corvus Pharmaceuticals is currently developing a selective, covalent inhibitor of ITK (soquelitinib), including in atopic dermatitis. In addition, Pfizer's ritlecitinib is reported to inhibit ITK and is approved for alopecia areata and is being developed for vitiligo, Crohn's disease and ulcerative colitis. In addition to these companies, Janssen Pharmaceuticals and AbbVie are co-marketing a small molecule inhibitor of the kinase BTK (ibrutinib) that has also been reported to inhibit ITK. Several companies are developing or have commercialized JAK inhibitors that may compete with ATI-2138, if approved, including Pfizer (tofacitinib, abrocitinib, and ritlecitinib), Eli Lilly/Incyte (baricitinib), and AbbVie (upadacitinib).

The commercial opportunity for our product 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 product candidates more rapidly than our potential third-party partners may obtain approval for our product candidates, which could result in our competitors establishing a strong market position before our product 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 product 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 ("USPTO") and its foreign counterparts.

With respect to our TSLP monoclonal antibody development program, we exclusively license pending applications in the United States, European Union, Japan and South Korea directed to TSLP monoclonal antibodies, including bosakitug, which, if issued, would naturally expire in 2040, subject to any applicable patent term adjustment or extension that may be available in a particular country. We also exclusively license a pending provisional application directed to methods of using TSLP monoclonal antibodies for the treatment of atopic dermatitis, which, if issued, would

naturally expire in 2045, subject to any applicable patent term adjustment or extension that may be available in a particular country.

With respect to our ITK inhibitor development program, we own numerous issued patents and pending applications in the United States and foreign countries directed to novel inhibitors of ITK, including ATI-2138, and methods of use that expire, or would expire, between 2035 and 2044, 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. We also own a pending international patent application filed under the Patent Cooperation Treaty (“PCT”) directed to methods of using ATI-2138, which if issued, would expire in 2043, subject to any applicable adjustment or extension. We also own pending PCT applications directed to crystal forms of ATI-2138 and to methods of synthesizing such ITK inhibitors, including ATI-2138, which if issued, would each expire in 2044, subject to any applicable adjustment or extension.

With respect to our bispecific antibody development program, we exclusively license a pending PCT application directed to such bispecific antibodies, including ATI-052, which, if issued, would naturally expire in 2043, subject to any applicable patent term adjustment or extension that may be available in a particular country.

With respect to our “soft” JAK inhibitor development program, we own numerous issued patents and pending applications in the United States and foreign countries to novel “soft” JAK inhibitors, various methods of use and synthesis that expire, or would expire, between 2038 and 2044, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own issued patents in the United States and China, as well as pending applications in the United States and foreign countries directed to various novel inhibitors of JAK1 and/or JAK3, including lezacitinib, and methods of using the same, which, if issued, would expire in 2038, subject to any applicable adjustment or extension. We also own pending applications in the United States and foreign countries directed to crystal forms of lezacitinib and directed to methods of using lezacitinib and topical formulations, which, if issued, would expire in 2041 and 2042, respectively, subject to any applicable adjustment or extension. We also own a pending PCT application directed to methods of synthesizing such novel inhibitors of JAK1 and/or JAK3, including lezacitinib, which, if issued, would expire in 2044, subject to any applicable adjustment or extension.

With respect to our MK2 signaling pathway inhibitor development program, we own numerous issued patents and pending applications to novel MK2 pathway inhibitors, including 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 in the European Union and Japan 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. We own a pending patent application in the United States directed to methods of treating various cancers, such as breast cancer and pancreatic cancer, by orally administering zunsemetinib, which, if issued, would expire in 2041, subject to any applicable adjustment or extension. Further, we own one U.S. patent and a pending patent application in the United States directed to certain methods of manufacturing zunsemetinib, as well as pending applications in the United States and Japan to crystal forms of zunsemetinib, which, if issued, would each expire in 2041, subject to any applicable adjustment or extension. We also exclusively license from Washington University pending applications in the United States and the European Union directed to methods of treating pancreatic cancer with MK2 inhibitors, including zunsemetinib, which, if issued, would expire in 2041, 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 is not subject to 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 product 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

Exclusive License Agreement with Biosion

In November 2024, we entered into an exclusive license agreement (the “Biosion Agreement”) with Biosion, pursuant to which we received exclusive rights to develop, manufacture and commercialize bosakitug and ATI-052 worldwide, excluding Mainland China, Macau, Hong Kong and Taiwan (“Greater China”). In connection with the Biosion Agreement, we also entered into a collaboration agreement (the “CTTQ Agreement”) with Biosion and CTTQ, a licensee of bosakitug in Greater China.

Under the Biosion Agreement and CTTQ Agreement, we agreed to pay, in the aggregate, \$30.0 million in upfront cash consideration, plus \$4.5 million for the reimbursement of certain development costs. We also issued warrants in the aggregate to purchase 14,281,985 shares of our common stock with an exercise price of \$0.00001 per share. The warrants are immediately exercisable, subject to any required overseas direct investment filings, and terminate when exercised in full. We also agreed to pay, in the aggregate (i) \$6.2 million for reimbursement of certain development costs and drug product material, (ii) up to \$125 million upon the achievement of specified regulatory milestones beginning with product approval, (iii) up to \$795 million upon the achievement of specified sales milestones, (iv) a tiered low-to-mid single digit royalty based upon a percentage of annual net sales, subject to specified reductions, and (v) a portion of any sublicense consideration received from granting sublicense or similar rights under any of the rights or licenses granted to us.

Agreement and Plan of Merger with Confluence

In August 2017, we entered into an Agreement and Plan of Merger (the “Confluence Agreement”) with Confluence, Aclaris Life Sciences, Inc., our wholly-owned subsidiary (“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. As part of the Confluence acquisition we acquired our investigational product candidates zunsemetinib, lepzacitinib and ATI-2138.

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 or biological product 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 and BLA Approval Processes

In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (“FDCA”) and its implementing regulations, and biologics under the FDCA, the Public Health Service Act (“PHSA”) and their implementing regulations. Drugs and biologics also are subject to other federal, state, local and foreign statutes and regulations. The process required by the FDA before new drug and biologic product candidates may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests, animal studies and formulation studies in compliance with the FDA’s good laboratory practice (“GLP”) regulations;
- submission to the FDA of an IND which must take effect before clinical trials may begin;
- approval by an independent institutional review board (“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 (“GCP”) regulations to establish the safety and efficacy of the proposed drug product for each indication;
- preparation and submission to the FDA of a New Drug Application (“NDA”) for a drug or a Biologics License Application (“BLA”) for a biologic, after completion of all pivotal trials;
- determination by the FDA within 60 days of its receipt of an NDA or BLA to file the application for review;
- review of the NDA or BLA by an FDA advisory committee, if applicable;
- satisfactory completion of one or more FDA inspections of the manufacturing facility or facilities at which the drug or biologic or its components are produced to assess compliance with current good manufacturing practices (“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 or BLA; 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 or biological product 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 or biological product candidate 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 drug or biological product candidate for specific targeted diseases and to determine dosage tolerance and optimal dosage.
- **Phase 3.** If a drug or biological product 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, to provide substantial evidence of efficacy, or purity and potency, and to further test for 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 drug or biological product candidate 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 or biologics 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 of an NDA or BLA.

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 or biological product candidate 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 or biologic, 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 or biologic.

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 or biologic 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 or biologic and the manufacturer must develop methods for testing the quality, purity and potency of the drug or biologic. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug or biological product 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 or BLA requesting approval to market the product. The submission of an NDA or BLA 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 and BLAs 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 or BLA for filing. In this event, the NDA or BLA 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 (“REMS”) is necessary to assure the safe use of the product. If the FDA concludes a REMS is needed, the sponsor of the NDA or BLA 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 a BLA to determine, among other things, whether the product is safe, pure and potent for its intended use. As part of the NDA and BLA review, the FDA also evaluates whether the manufacturing of the drug or biologic product candidate is cGMP-compliant to assure and preserve the product’s identity, strength, quality, and purity. The FDA may refer the NDA or BLA 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 and BLAs receive either standard or priority review. A drug or biological product candidate 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 or BLA from ten months to six months from filing of the NDA or BLA. After the FDA evaluates the NDA or BLA and conducts inspections of manufacturing facilities where the drug or biological product candidate 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 or biologic 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 or BLA does not satisfy the criteria for approval.

Post-approval Requirements

Drugs and biologics 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 and biologic manufacturers and other entities involved in the manufacture and distribution of approved products 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 and biologic 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 and biological products that are placed on the market. Drugs and biologics 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 product 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 ("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 ("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.

Biosimilars and Exclusivity

The Biologics Price Competition and Innovation Act of 2009 ("BPCIA") created an abbreviated approval pathway in the PHSA for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Biosimilarity, which requires that there be no clinically meaningful differences between the biological

product and the reference product in terms of safety, purity, and potency, can be shown through, as applicable, analytical studies, animal studies, and a clinical study or studies. Interchangeability means that a product is biosimilar to the reference product and can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing that applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product. The BPCIA also established an exclusivity period for biosimilars approved as interchangeable products. Substitution at the pharmacy level of biosimilar products deemed to be interchangeable is governed by state pharmacy law.

A biological product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity protection. This six-month exclusivity, which runs from the end of other exclusivity protection, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study.

Regulation Outside of the United States

Even if we obtain FDA approval for a drug or biological product 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 product 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 ("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 ("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 ("CHMP") of the European Medicines Agency ("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 product 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 product 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 (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 (“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 (“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 (“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.

There have been executive branch, judicial and Congressional challenges and amendments to certain aspects of the Affordable Care Act. On August 16, 2022, the Inflation Reduction Act of 2022 (“IRA”) was signed into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the “donut hole” under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to additional challenges and amendments in the future. It is unclear how such challenges and any additional health care reform measures of the second Trump 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, will stay in effect through 2032 unless additional Congressional action is taken.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drug and biologic products. For example, the IRA, among other things, (1) directs the Department of Health and Human Services (“HHS”) to negotiate the price of certain single-source drugs and biologics that have been on the market for at least 7 years covered under Medicare (the “Medicare Drug Price Negotiation Program”) and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, which take effect in January 2026. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. The effect of reducing prices and reimbursement for certain of our product candidates, if approved, could significantly impact our business and consolidated results of operations. In addition, the IRA may meaningfully influence our pharmaceutical industry business strategies. In particular, it may reduce the attractiveness of investment in small molecule and biologic innovation.

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. For example, on January 5, 2024, the FDA approved Florida’s proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear if and how this program will be implemented and whether it will be subject challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. Any such approved importation plans, if implemented, may result in lower drug prices for products covered by those programs.

The Affordable Care Act, the IRA, as well as other federal and state health care reform measures that have been and may be adopted in the future, could harm our future revenue. Additional legislative actions may be taken in the future which may change current regulations, guidance and interpretations. The impact of such actions on our business, if any, cannot presently be determined.

The Hatch Waxman Amendments to the 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 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 product 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 or BLA licensure, 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 (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 or BLA submission, and all of the review phase, which is the time between NDA or BLA 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 product 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 product 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 product candidates, if approved. Our product 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 product candidates, if approved, on a competitive and profitable basis. For example, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics that have been on the market for at least 7 years covered under Medicare, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. Our results of operations could be adversely affected by the Affordable Care Act, the IRA and by other health care reforms that may be enacted or adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections. 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 product 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 product 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 product 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 product to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our product 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, 2024, we had 64 total employees, of which 61 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 701 Lee Road, Suite 103, 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 (“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.
- We have a limited history as a clinical-stage biopharmaceutical company developing and partnering our product 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 product 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 product 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 rely heavily on third parties for clinical trials, manufacturing, and development support. Their performance impacts our timelines and success.
- If we are unable to obtain and maintain patent protection for our product 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 product 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 \$132.1 million and \$88.5 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, we had an accumulated deficit of \$902.9 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 product candidates, including preclinical studies and clinical trials. 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 product candidates;
- continue to develop our product candidates;
- continue to discover and develop additional product 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 product candidates and pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, for the further development and/or commercialization of our product candidates, as well as discovering and developing additional product 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 product candidates that is significant enough to achieve profitability.

For any of our product 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 product 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 product candidates, any partnerships we enter into do not result in the successful development, marketing approval for and commercialization of our product 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 product candidates, even if the product 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 product candidates or the identification and consummation of transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product 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 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 product 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 product candidates. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product 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 product candidates, and our product candidates, if approved, may not achieve commercial success. Furthermore, we incur and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses.

As of December 31, 2024, we had cash, cash equivalents and marketable securities of \$203.9 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 products or product candidates, and changes in regulation. Our future capital requirements will depend on many factors, including:

- the number and development requirements of the product candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our product candidates;

- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we in-license or acquire product candidates and technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product candidates; and
- our ability to earn revenue from licenses to, or partnerships or other arrangements with, third parties.

We will require additional capital to develop our product candidates 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 caused by a variety of factors including geopolitical tensions and inflationary pressures. 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 product candidates, we could be forced to curtail our planned operations.

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 product 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 product 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 product candidates that we would otherwise prefer to develop ourselves.

We have a limited history as a clinical-stage biopharmaceutical company developing and partnering our product 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 product 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 product 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 product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other known or unknown factors in achieving our business objectives.

Certain estimates of market opportunity and forecasts may prove to be smaller than we believe.

The estimates of market opportunity and forecasts of market growth included in documents that we file with the SEC may prove to be smaller than we believe, and even if the markets in which we compete achieve the forecasted growth, our business may not grow at similar rates, or at all. Our projections of addressable patient populations within the indications we pursue are based on our estimates and independent market research, industry and general publications obtained from third parties. Market opportunity estimates and growth forecasts included in this Annual Report and the other documents that we file with the SEC are subject to significant uncertainty and are based on assumptions and estimates. These estimates, which have been derived from a variety of sources, including scientific literature and market

research, may prove to be incorrect. Further, new studies may change the estimated incidence or prevalence of these indications. Additionally, the potentially addressable patient population may not ultimately be amenable to treatment with our product candidates. Our market opportunity may also be limited by current and future products of our competitors that are already available in the market or may enter the market for such patients. If any of our estimates prove to be inaccurate, the market opportunity for our product candidates could be significantly diminished and have an adverse material impact on our business.

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

Biologics carry unique risks and uncertainties, which could have a negative impact on future results of operations.

The successful discovery, development, manufacturing and sale of biologics is a long, expensive and uncertain process. There are unique risks and uncertainties with biologics. For example, access to and supply of necessary biological materials, such as cell lines, may be limited and governmental regulations restrict access to and regulate the transport and use of such materials. In addition, the development, manufacturing and sale of biologics is subject to regulations that are often more complex and extensive than the regulations applicable to other pharmaceutical products. Manufacturing biologics, especially in large quantities, is often complex and may require the use of innovative technologies. The types of analytical development data necessary for verifying structural biocomparability when changing manufacturing sites is also more difficult and complex to generate for biologics than for other pharmaceutical products. Such manufacturing also requires facilities specifically designed and validated for this purpose and sophisticated quality assurance and quality control procedures. Biologics are also frequently costly to manufacture because production inputs are derived from living animal or plant material, and some biologics cannot be made synthetically. In addition, the regulatory scrutiny of and landscape for the chemistry, manufacturing and analytical controls information is also considered to be more complex for biologics than other pharmaceutical products. Failure to successfully discover, develop and manufacture our biological product candidates would adversely impact our business and future results of operations.

We may not be successful in our efforts to identify and develop additional product candidates, including through leveraging our KINect drug discovery platform.

A key element of our approach is to identify and develop additional novel product candidates, including through leveraging our KINect drug discovery engine. Our platform is powered by a unique combination of our proprietary chemical library of kinase inhibitors, our novel approaches to inhibitor modalities, our expertise in SBDD, and our custom kinase assays. Our ability to identify and develop additional product candidates is subject to numerous risks, including that:

- our drug discovery methods and our KINect platform may not be successful in identifying additional product candidates;
- our discovery programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development; and
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be product candidates that will receive marketing approval and achieve market acceptance.

In addition, discovery programs require substantial technical, financial and human resources. We may not be able to maintain sufficient resources and expertise to discover additional product candidates. It could take years to identify a viable product candidate, and there is a risk that we may never do so. If we are unable to identify successful product candidates for preclinical and clinical development and regulatory approval in a timely matter 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 product candidates, which could harm our business.

If we are unable to successfully develop our product 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 product 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 product candidates and the identification of potential product candidates. Our ability to earn substantial revenue from our product 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 product candidates. The success of any product candidates that we develop 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 product candidates;
- the commercial launch of our product candidates, if approved, by a potential third-party partner;
- our potential third-party partners' ability to achieve acceptance of our product candidates, if approved, by patients, the medical community and third-party payors, and willingness of patients to pay out of pocket for our product 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 product candidates, if approved;
- the prevalence and severity of adverse events experienced with our product candidates;
- the availability, perceived advantages, cost, safety and efficacy of alternative treatments for the proposed indications of our product candidates;
- obtaining and maintaining patent, trademark and trade secret protection and regulatory exclusivity for our product candidates and otherwise protecting the intellectual property portfolio;
- maintaining compliance with regulatory requirements, including 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 product 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 product candidates' success in clinical trials will not guarantee marketing approval. Following submission, the NDA or BLA for any product 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 product 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 product 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 product 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 our product candidates or pursuing strategic alternatives, including identifying and consummating transactions with third-party partners, to further develop, obtain marketing approval for and/or commercialize our product candidates.

The risk of failure for our product candidates is high. It is impossible to predict when or if any of our product candidates will prove effective or safe in humans or will receive marketing approval. Before obtaining regulatory approval for the sale of any product candidate, we must complete preclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product 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. For example, in 2023 we announced that zunezetinib failed to meet the endpoints in Phase 2 trials in rheumatoid arthritis and hidradenitis suppurativa, following which we discontinued further development of our MK2 inhibitor programs in immuno-inflammatory diseases. 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 product candidates performed satisfactorily in preclinical studies and clinical trials have nonetheless failed to obtain marketing approval of their drugs.

Additionally, we may utilize an “open-label” clinical trial design. For example, our current Phase 2a trial of ATI-2138 is an “open-label” trial. An “open-label” clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate or either an existing approved drug or placebo. Most open-label clinical trials test only the investigational product candidate and sometimes may do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. Open-label clinical trials may be subject to a “patient bias” where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open-label clinical trials may be subject to an “investigator bias” where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open-label trial may not be predictive of future clinical trial results of a product candidate when studied in a controlled environment with a placebo or active control.

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 product 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 (“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 product 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 product 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;
- patients or clinical trial investigators may not comply with or may deviate from the clinical trial protocol, including failing to follow specified testing procedures, schedules, or other protocol requirements, which could impact the integrity of clinical trial data and potentially jeopardize the trial;
- while a product candidate may show evidence of clinical activity, we may experience a high placebo effect which will make it difficult to show a statistically significant effect of the product candidate as compared to the control arm;

- our product 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 product candidates may be greater than we anticipate; and
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product 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 product candidates, our costs will increase, our product candidate development process will be slowed, the commercial prospects of our product 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 product 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 product candidates. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product 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 product candidates, and our potential third-party partners may:

- be delayed in obtaining marketing approval for our product 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 product 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 product 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 product 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. We may not be able to initiate or

continue clinical trials for our product 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 product 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 subjects adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective subjects.

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 product 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 product candidates.

Our clinical trials may fail to demonstrate the safety and efficacy of our product candidates, or serious adverse or unacceptable side effects may be identified during the development of our product candidates, which could increase our costs or necessitate the abandonment or limitation of the development of our product 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 product candidates.

If our product 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 product candidates. Many product candidates that initially showed promise in early-stage testing have later been found to cause side effects that prevented further development of the product candidate.

Before any potential third-party partners can obtain marketing approvals for the commercial sale of our product candidates, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that our product 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 product candidate studied for the target indication.

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

- we may need to abandon the development or limit the further development of our product 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 product 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 product 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 product 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 product 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, product 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 product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.

Changes in methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product 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 product 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 product 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 product candidates.

We have conducted and may in the future conduct clinical trials for our product candidates outside the United States. The FDA, EMA or comparable foreign regulatory authorities may not accept data from such trials.

We have conducted and may in the future conduct clinical trials for our product candidates outside the United States. In addition, our partners may conduct clinical trials for our product candidates outside of the United States that we or our potential third-party partners may try to leverage to seek marketing approval in 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. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U.S. population and U.S. medical practice, the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations, and the FDA can validate the data through on-site inspections or other appropriate means. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. 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 product candidates not receiving approval or clearance for commercialization in the applicable jurisdiction.

In addition, any escalation of political tensions, economic instability, military activity or civil hostilities outside the United States could disrupt our ability to conduct trials outside of the United States, or delay or adversely affect the timeliness of such trials. This could result in the need for alternative trial sites, which could be costly and time-consuming and delay the clinical development of our product candidates.

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

A key element of our strategy is to build and expand our pipeline of product candidates. To build our pipeline, we may seek to in-license or acquire additional product candidates, in addition to our in-house capabilities. We may not be able to identify or develop product candidates that are safe, tolerable and effective. Even if we are successful in continuing to build our pipeline, the potential product 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 receive marketing approval and achieve market acceptance.

We may expend our limited resources to pursue a particular product candidate or indication and fail to capitalize on product 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 product candidates that we identify for specific indications or therapeutic areas. As a result, we may forego or delay pursuit of opportunities with other product candidates or for other indications or therapeutic areas that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or profitable market opportunities. Our spending on current and future development programs and product candidates for specific indications or therapeutics areas may not yield any commercially viable products. If we do not accurately evaluate the commercial potential or target market for a particular product candidate, we may relinquish valuable rights to that product 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 product candidate.

For any of our product 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 product 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 product candidates, we may not earn significant

revenue and we may not become profitable. The degree of market acceptance of any product 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 product 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.

For our product candidate bosakitug targeting TSLP, we face direct competition from companies developing TSLP-targeted therapies, including Amgen and AstraZeneca (tezepelumab), KeyMed Biosciences (CM-326), Uniquity Bio (solrikutig), Windward Bio (WIN378), Tavotek Biotherapeutics (TAVO101), GSK (GSK5784283), and UpStream Bio (verekutig). As a potential treatment of atopic dermatitis with bosakitug, we compete with companies marketing or developing biologics, JAK inhibitors and other therapeutic classes, including AbbVie (upadacitinib), Incyte (ruxolitinib), LEO Pharma A/S (delgocitinib), Pfizer (crisaborole; abrocitinib), Eli Lilly (lebrikizumab), Dermavant Sciences (tapinarof), and Regeneron Pharmaceuticals and Sanofi (dupilumab). We also compete with these and other companies with respect to other indications of interest for bosakitug, including asthma, CRSwNP and COPD.

For ATI-2138, our dual ITK/JAK inhibitor product candidate, we face competition from companies developing selective ITK inhibitors such as Corvus Pharmaceuticals (soquelitinib), as well as companies marketing or developing JAK inhibitors including Pfizer (tofacitinib, abrocitinib, and ritlecitinib), Eli Lilly/Incyte (baricitinib), and AbbVie (upadacitinib). We also compete with these and other companies marketing or developing other therapeutic classes with respect to indications of interest for ATI-2138, including atopic dermatitis, alopecia areata and vitiligo.

The commercial opportunity for our product 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 product 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 product candidates, which could result in our competitors establishing a strong market position before our product 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 product 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 product 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 product candidates, if approved. Our product 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 product candidates, if approved, on a competitive and profitable basis. For example, the IRA among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics that have been on the market for at least 7 years covered under Medicare, and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. Our results of operations could be adversely affected by the Affordable Care Act, the IRA, and by other health care legislative reforms that may be enacted or adopted in the future, particularly in light of the recent U.S. Presidential and Congressional elections. 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 product 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 product 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 product 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 product candidate to other available therapies. Such pharmacoeconomic studies can be costly and the results uncertain. Our business could be harmed if reimbursement of our product 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 product 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 product candidates in human clinical trials and 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 product candidates, caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for any product 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 product 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 product 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 product 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 product candidates. Consequently, our results of operations and the commercial prospects for our product 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 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 product candidates or commercialization of our product candidates, if approved, producing additional losses and depriving us of potential revenue.

We contract with third parties for the manufacture and supply of our product candidates for preclinical and clinical testing. This reliance on third parties increases the risk that we will not have sufficient quantities of our product 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 have not developed the ability to manufacture drug product ourselves, nor have we developed the capabilities to manufacture biologics. We currently rely, and expect to continue to rely, on third parties for the manufacture and supply of our product candidates for preclinical and clinical testing. This reliance on third parties increases the risk that we will not have sufficient quantities of our product 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.

We currently use manufacturers in China to manufacture certain product candidates for use in our clinical trials. For example, we currently rely on WuXi Biologics (Hong Kong) Limited (“WuXi”) for the production of product necessary to complete our upcoming clinical trial for bosakitug. There have been Congressional legislative proposals, such as the bill titled the BIOSECURE Act, which would, among other things, prohibit U.S. federal funding in connection with biotechnology equipment or services produced or provided by certain named Chinese “biotechnology companies of concern” (which includes WuXi) and loans and grants to, and federal contracts with, any entity that uses biotechnology equipment or services from one of these entities in performance of the government contract, grant, or loan. The legislation would also give the federal government the authority to name additional “biotechnology companies of concern” that are engaged in research activities with the Chinese government and that pose a risk of U.S. national security. We continue to monitor the status of the BIOSECURE Act, the implementation of which could materially impact our agreement with WuXi or other Chinese companies. If this or similar legislation is adopted, or additional manufacturers are added to the list of companies of concern, we may need to find replacement manufacturers, which we may not be able to do on a timely basis, the result of which could delay, prevent or impair our ability to timely conduct our clinical trials or our other development efforts and adversely affect our business.

The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA or comparable foreign regulatory authorities pursuant to inspections that will be conducted after the NDA, BLA 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 product 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 product 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

- product 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 product candidates.

Our product candidates may compete with other products and product 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 product candidates. Additionally, the loss of or damage to our cell banks maintained at these third-party manufacturers could significantly delay our development efforts, as establishing and qualifying new cell banks would require substantial time and resources.

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 product 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 product 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 product 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 product candidates. If those arrangements are not successful, we may not be able to capitalize on the market potential of these product 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 product 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 product 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 product 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 product 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 product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- partners could independently develop, or develop with third parties, products that compete directly or indirectly with our product 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;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own products or product candidates, which may cause our partners to cease to devote resources to the development and/or commercialization of our product candidates, if approved;
- a partner with marketing and distribution rights to one or more of our product candidates that achieve marketing approval may not commit sufficient resources to the marketing and distribution of such product 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 product candidates, might lead to additional responsibilities for us with respect to product 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 product candidates.

Partnership agreements may not lead to development, marketing approval or commercialization of product 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 development programs for our product candidates will require substantial additional capital. We intend to partner with pharmaceutical and biotechnology companies for the further development and/or commercialization of our product 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 product candidate, the costs and complexities of manufacturing and delivering such product 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 product 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 product 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 product candidate, 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 product candidates or bring them to market and generate revenue.

We may not have access to all information regarding our product candidates that are subject to partnership agreements. Consequently, our ability to inform our stockholders about the status of our product 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 product candidates that are or may in the future 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 partners or potential partners. In addition, we have and may in the future have confidentiality obligations under our agreements with such partners. Therefore, our ability to keep our stockholders informed about the status of our product 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. For example, we are relying on CTTQ, our partner in China, to share information about its Phase 2 trials of bosakitug in respiratory diseases. If our partners do not timely inform us about the status of our product candidates that are the subject of the partnership, we may make operational and investment decisions that we would not have made had we been fully informed, which may have an adverse impact on our business, prospects, financial condition and results of operations.

We are dependent on third parties accurately generating and reporting data related to our product candidates, and their conduct could adversely affect our business.

We have and may in the future acquire or in-license our product candidates at various stages of development. For example, we in-licensed bosakitug and ATI-052 from Biosion. Our assumptions about the potential of such product candidates are partially based on data generated from preclinical studies and clinical trials conducted by Biosion. We are dependent on Biosion having conducted its research and development in accordance with the applicable protocols, informed consent, legal and regulatory requirements, and scientific standards, having accurately reported the results of all studies conducted, and having correctly collected the data from these studies. If these activities were not compliant, accurate or correct, the clinical development, regulatory approval or commercialization of such product candidates will be adversely affected.

Additionally, in cases where third parties conduct clinical trials using our product candidates through partnership or licensing agreements, we face additional risks related to the conduct and outcome of those trials that are outside of our direct control. For example, issues such as poor data integrity, safety concerns, protocol violations, or failure to meet endpoints in these third-party trials could adversely impact the development timeline and regulatory approval process for those product candidates in other indications or territories, require additional studies, create negative market perception affecting future commercial potential, impact our ability to pursue strategic alternatives for such product candidates, or result in increased regulatory scrutiny across our programs.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain patent protection for our product 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 product 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 product candidates. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product 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 product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and product 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 USPTO or other foreign patent office, or become involved in opposition, central revocation, 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 product 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 product 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 product candidates.

Even if our patent applications 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 product candidates, or limit the duration of the patent protection of our technology and product candidates. Our pending U.S. application covering bosakitug, if issued, would expire in 2040 and our pending PCT application covering ATI-052, if issued, would expire in 2043. Our issued U.S. patent directed to ATI-2138 expires in 2039. Our issued U.S. patent covering lepzacitinib expires in 2038. Our issued U.S. patents covering zunsemetinib expire in 2034. We are pursuing additional patent protection for our product candidates, such as methods of use, polymorphs and methods of manufacture, that may extend the term of patent protection in select countries. Given the amount of time required for the development, testing and regulatory review of new product 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, or similar requirements outside of the United States. 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 product 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 or derivation 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 product 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, we only have pending applications in the United States, Europe, Japan and South Korea for our TSLP monoclonal antibodies. We have issued U.S. patents directed to ATI-2138, and pending applications in foreign markets directed to ATI-2138. We currently have a pending PCT application directed to ATI-052 and other TSLP and IL4R bispecific antibodies. While we have issued U.S. and Chinese patents directed to lepzacitinib, we do not currently have any patents in other foreign markets; rather, we have pending applications in other foreign markets directed to lepzacitinib. Zunsemetinib is currently covered by patents and applications in the United States, European Union and other foreign markets.

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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product 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 product candidates can be challenged by competitors.

If any of our product candidates advance through development or are approved by the FDA or foreign regulatory authority, one or more third parties may challenge the current patents, or patents that may issue in the future, within our portfolio covering these product 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 or a patent infringement suit arising out of the filing of an abbreviated biologics license application (“aBLA”). 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 product 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 product 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 product 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, product candidates and our target indications. Our pending U.S. application covering bosakitug, if issued, would expire in 2040. Our issued U.S. patent directed to ATI-2138 expires in 2039. Our pending PCT application covering ATI-052, if issued, would expire in 2043. Our issued U.S. patent covering lepzacitinib expires in 2038. Our issued U.S. patents covering zunsemetinib expire in

2034. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting our product 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 product candidates, one or more of our U.S. patents may be eligible for limited patent term extension under the Hatch-Waxman Act for a product 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. Similar provisions are available in certain foreign countries, such as the European Union and Japan.

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 product 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.

For example, following the result of a referendum in 2016, the United Kingdom left the European Union on January 31, 2020, commonly referred to as Brexit. The impact of the withdrawal of the United Kingdom from the European Union will not be known for some time, which could lead to a period of uncertainty relating to our ability to obtain and maintain patents and trademarks in the United Kingdom. In 2012, the European Patent Package ("EU Patent Package") regulations were passed with the goal of providing for a single pan-European Unitary Patent, and a new European Unified Patent Court ("UPC") for litigation of European patents, which was implemented in 2023. All European patents, including those issued prior to ratification, would by default automatically fall under the jurisdiction of the UPC and allow for the possibility of obtaining pan-European injunctions, unless the patent holder "opts out" of the UPC on a patent-by-patent basis during an initial seven-year period. Owners of traditional European patent applications who receive notice of grant after the EU Patent Package ratification can either accept a Unitary Patent or validate the patent nationally and file an opt-

out demand. The EU Patent Package may increase the uncertainties and costs surrounding the enforcement or defense of our issued European patents and pending applications. The full impact on future European patent filing strategy and the enforcement or defense of our issued European patents in member states and/or the UPC is not known.

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 Product 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 product 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 product 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 product candidate will prevent our potential third-party partners from commercializing the product 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 product 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 product 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 product 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 product 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 product 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 product candidates, the commercial prospects for our product 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 product candidates from being marketed abroad.

In order to market and sell our product candidates 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 product candidates in any market.

A variety of risks associated with marketing our product candidates by our potential third-party partners internationally could harm our business.

If our product 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 (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 product 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 product candidates.

Any product 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 product candidates, when and if any of them are approved.

Any product 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 product 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 product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product 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 product 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 product candidates, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may have negative consequences, including:

- restrictions on such product candidates, manufacturers or manufacturing processes;
- restrictions on the labeling or marketing of a product;
- restrictions on drug distribution or use;
- requirements to conduct post-marketing studies or clinical trials;
- warning letters;
- recall or withdrawal of the products 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 products;
- 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 products 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 product 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 product 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 product 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 product 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 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 product 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 product 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 product candidates.

Recently enacted and future legislation may increase the difficulty and cost for our potential third-party partners to obtain marketing approval of our product candidates and commercialize our product 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 product candidates, restrict or regulate post-approval activities and affect our potential third-party partners' ability to profitably sell any of our product 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 product 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.

There have been executive branch, judicial and Congressional challenges and amendments to certain aspects of the Affordable Care Act. For example, on August 16, 2022, President Biden signed the IRA into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in Affordable Care Act marketplaces through plan year 2025. The IRA also eliminates the "donut hole" under the Medicare Part D program

beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and through a newly established manufacturer discount program. It is possible that the Affordable Care Act will be subject to additional challenges and amendments in the future. It is unclear how such challenges and any additional health care reform measures of the second Trump 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 2032 unless additional Congressional action is taken. 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 product 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 product 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 product candidates, if approved, which in turn may impact our ability to earn revenue from arrangements with such third-party partners for our product candidates.

Legislative and regulatory proposals have been made to expand post-approval requirements and restrict sales and promotional activities for drug and biologic products. For example, the IRA, among other things, (1) directs HHS to negotiate the price of certain single-source drugs and biologics that have been on the market for at least 7 years covered under Medicare and (2) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. These provisions took effect progressively starting in fiscal year 2023, although the Medicare Drug Price Negotiation Program is currently subject to legal challenges. On August 15, 2024, HHS announced the agreed-upon prices of the first ten drugs that were subject to price negotiations, which take effect in January 2026. HHS will select up to fifteen additional products covered under Part D for negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program. On December 7, 2023, the Biden administration announced an initiative to control the price of prescription drugs through the use of march-in rights under the Bayh-Dole Act. On December 8, 2023, the National Institute of Standards and Technology published for comment a Draft Interagency Guidance Framework for Considering the Exercise of March-In Rights which for the first time includes the price of a product as one factor an agency can use when deciding to exercise march-in rights. While march-in rights have not previously been exercised, it is uncertain if that will continue under the new framework. It is unclear whether these or similar policy initiatives will be implemented in the future. The effect of reducing prices and reimbursement for certain of our product candidates, if approved, could significantly impact our business and consolidated results of operations. In addition, the IRA may meaningfully influence our and pharmaceutical industry business strategies. In particular, it may reduce the attractiveness of investment in small molecule and biologic innovation. Further, we expect additional health reform measures may be implemented in the future, particularly in light of the recent U.S. Presidential and Congressional elections.

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. For example, on January 5, 2024, the FDA approved Florida's proposal to import certain drugs from Canada for specific state healthcare programs. It is unclear if and how this program will be implemented and whether it will be subject challenges in the United States or Canada. Other states have also submitted proposals that are pending review by the FDA. Any such approved importation plans, if implemented, may result in lower drug prices for products covered by those programs. 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 product 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 product candidates.

Our biological product candidates may face competition sooner than anticipated.

The BPCIA created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the applicant's own preclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of its product.

Bosakitug and ATI-052, if approved, may not qualify for the 12-year period of exclusivity, which allows the FDA to approve a biosimilar product any time after the reference product was first licensed by the FDA. Even if the reference product exclusivity is awarded upon licensure by FDA, there is a risk that this exclusivity could be shortened due to Congressional action or otherwise, or that the FDA will not consider bosakitug or ATI-052 to be reference products for competing products, potentially creating the opportunity for competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. If we cannot obtain exclusivity for bosakitug and ATI-052 under the BPCIA, we could face competition sooner than anticipated, which could harm our business.

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 product candidate to other available procedures. If reimbursement of our product candidates is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our potential third-party partners may not be able to generate revenue, which in turn may adversely affect our ability to earn revenue from arrangements with such third-party partners for our product 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 and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, and rules, contractual obligations, industry standards, policies and other obligations related to data privacy and security. Our actual or perceived failure (or that of the third parties with whom we work) to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, “process”) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, personnel data, data from participants in our clinical trials, and other sensitive third-party data (collectively, “sensitive data”). Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, industry standards, external and internal privacy and security policies, contractual requirements, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal data privacy laws, consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws). Numerous U.S. states have enacted comprehensive privacy laws that impose certain obligations on covered businesses, including providing specific disclosures in privacy notices and affording residents with certain rights concerning their personal data. As applicable, such rights may include the right to access, correct, or delete certain personal data, and to opt-out of certain data processing activities, such as targeted advertising, profiling, and automated decision-making. The exercise of these rights may impact our business operations. Certain states also impose stricter requirements for processing certain personal data, including sensitive information, such as conducting data privacy impact assessments. These state laws allow for statutory fines for noncompliance. For example, the California Consumer Privacy Act of 2018 (“CCPA”), applies to personal data of consumers, business representatives, and employees who are California residents, and requires businesses to provide specific disclosures in privacy notices and honor requests of such individuals to exercise certain privacy rights. The CCPA provides for fines and allows private litigants affected by certain data breaches to recover significant statutory damages. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Similar laws are being considered in several other states, as well as at the federal and local levels, and we expect more states to pass similar laws in the future. While these laws in other states, like the CCPA, exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

In addition to “comprehensive” state privacy laws like CCPA, we are currently and may become in the future subject to new state laws governing the privacy of consumer health data. For example, Washington’s My Health My Data Act broadly defines consumer health data, places restrictions on processing consumer health data (including imposing stringent requirements for consents), provides consumers certain rights with respect to their health data, and creates a private right of action to allow individuals to sue for violations of the law. Other states are considering and may adopt similar laws.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union’s General Data Protection Regulation (“EU GDPR”) and the United Kingdom’s GDPR (“UK GDPR”) impose strict requirements for processing personal data. For example, under GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the EEA and the United Kingdom (“UK”) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in

compliance with law, such as the EEA's standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, and the EU-U.S. Data Privacy Framework and the UK extension thereto (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Framework), these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Regulators in the United States such as the Department of Justice are also increasingly scrutinizing certain personal data transfers and have proposed and may enact certain data localization requirements, for example, the Biden Administration's executive order Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may in the future become subject to additional obligations. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies and make other statements concerning data privacy and security. Regulators in the United States are increasingly scrutinizing these statements, and if these policies or statements are found to be deficient, lacking in transparency, deceptive, unfair, misleading, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security (and consumers' data privacy expectations) are quickly changing, becoming increasingly stringent, and creating uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for significant statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; or stoppages in our business operations (including clinical trials); inability to process personal data or to operate in certain jurisdictions; limited ability to develop our product candidates; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

We are subject to governmental economic sanctions laws 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 product 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 product 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 product 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 product 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, Hugh Davis, Ph.D, our Chief Operating Officer and President, Kevin Balthaser, 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.

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 product 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.

In addition, we have a hybrid work model of remote and in-person operations for our employees that enables us to continue to develop our product candidates and provide contract research services to our clients. The effects of our hybrid work model may negatively impact productivity, disrupt our business and delay our preclinical drug development and clinical trials and timelines. These and similar, and perhaps more severe, disruptions in our operations could negatively impact our business, operating results and financial condition.

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 product candidates;
- any delay in our regulatory filings for any of our product 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 product candidates to receive marketing approval;
- unanticipated serious safety concerns related to the use of any product candidate or previously sold commercial product;
- changes in financial estimates by us or by any securities analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the structure of health care payment systems;
- changes in the market valuations of similar companies;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biotechnology industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

In the past, stockholders have initiated class action lawsuits against 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.

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

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

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

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.

Further, we have in the past and may in the future issue equity securities in connection with financings, acquisitions or other strategic investments. Any such issuances of additional capital stock may cause stockholders to experience significant dilution of their ownership interests and the per share value of our common stock to decline.

Provisions in our corporate charter documents and under Delaware law may prevent or frustrate attempts by our stockholders to change our management and hinder efforts to acquire a controlling interest in us, and the market price of our common stock may be lower as a result.

There are provisions in our certificate of incorporation and bylaws that may make it difficult for a third party to acquire, or attempt to acquire, control of our company, even if a change of control was considered favorable by some or all of our stockholders. For example, our board of directors has the authority to issue up to 10,000,000 shares of preferred stock. The board of directors can fix the price, rights, preferences, privileges, and restrictions of the preferred stock without any further vote or action by our stockholders. The issuance of shares of preferred stock may delay or prevent a change of control transaction. As a result, the market price of our common stock and the voting and other rights of our stockholders may be adversely affected. An issuance of shares of preferred stock may result in the loss of voting control to other stockholders.

Our charter documents also contain other provisions that could have an anti-takeover effect, including:

- only one of our three classes of directors is elected each year;
- stockholders are not entitled to remove directors other than by a 66 2/3% vote and only for cause;
- stockholders are not permitted to take actions by written consent;
- stockholders cannot call a special meeting of stockholders; and
- stockholders must give advance notice to nominate directors or submit proposals for consideration at stockholder meetings.

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

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, 2024, we had federal and state net operating loss carryforwards (NOLs) of \$469.4 million and \$401.1 million, respectively, which will begin to expire in 2032. Under federal law, federal NOL carryforwards generated in tax years beginning after December 31, 2017 may be carried forward indefinitely but may only be used to offset 80% of our taxable income annually. It is uncertain if and to what extent various states will conform to the federal tax law. As of December 31, 2024, we also had federal research and development tax credit carryforwards of \$21.9 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 2030. These NOL 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. Although we have experienced Section 382 ownership changes between 2012 and 2024, we have concluded that we should have sufficient ability to utilize NOLs accumulated during the periods tested. In addition, we may have experienced ownership changes since 2024 and 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 NOL 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.

Our holders of 5% or more of our capital stock collectively own a significant percentage of our outstanding common stock and have the ability to exert significant control over matters subject to stockholder approval.

Our holders of 5% or more of our capital stock collectively own a significant percentage of our outstanding common stock. As a result, these holders, if acting together, have significant influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, amendment of our organizational documents, any merger, consolidation or sale of all or substantially all of our assets and any other significant corporate transaction. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that conflicts of interest may exist or arise.

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

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

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

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

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

General Risk Factors

If our information technology systems, those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats that could cause security incidents.

Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer “hackers,” threat actors, “hacktivists,” organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to develop our product candidates and provide our services.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks, credential stuffing, credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, attacks enhanced or facilitated by AI, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, ability to develop our product candidates or provide our services, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities’ systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, SaaS platforms, encryption and authentication technology, employee email and other functions. We also rely on third-party service providers to provide other products and services, or otherwise to operate our business. Our ability to monitor these third parties’ information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties’ infrastructure in our supply chain or our third-party partners’ supply chains have not been compromised.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps designed to detect, mitigate, and remediate vulnerabilities in our information systems (such as our hardware and/or software). We may not, however, detect and remediate all such vulnerabilities including on a timely basis. It may be difficult and/or costly to detect, investigate, mitigate, contain, and remediate a security incident, and our efforts to do so may not be successful. Further, we may experience delays in developing and deploying remedial measures and patches designed to address identified vulnerabilities. Vulnerabilities could be exploited and result in a security incident. Actions taken by us or the third parties with whom we work to detect, investigate, mitigate, contain, and remediate a security incident could result in outages, data losses, and disruptions of our business. Threat actors may also gain access to other networks and systems after a compromise of our networks and

systems. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future.

Any of the previously identified or similar threats has caused and, in the future, could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to operate our business.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations has required and may in the future require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

Applicable data privacy and security obligations may require us to notify relevant stakeholders, including affected individuals, customers, regulators, and investors, of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; diversion of management attention; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may prevent or cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive data about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

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.

Unfavorable conditions, including inflationary pressure, in the global economy could limit our ability to grow our business and negatively affect our operating results.

General worldwide economic conditions have experienced significant instability in recent years including the recent global economic uncertainty and financial market conditions. For example, inflation rates, particularly in the United States and United Kingdom, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. Additionally, financial markets around the world have experienced volatility in connection with geopolitical conflicts. These conditions make it extremely difficult for us to accurately forecast and plan future business activities.

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 200,000,000 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, the Inflation Reduction Act provides for a minimum tax equal to 15% of the adjusted financial statement income of certain large corporations, as well as a 1% excise tax on certain share buybacks by public corporations that would be imposed on such corporations. In addition, it is uncertain if and to what extent various states will conform to 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 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 if we cease to 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.

Artificial intelligence presents risks and challenges that can impact our business including by posing security risks to our confidential information, proprietary information, and personal data.

Issues in the development and use of artificial intelligence, combined with an uncertain regulatory environment,

may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, artificial intelligence presents risks and challenges that could impact our business. We may adopt and integrate generative artificial intelligence tools into our systems. Our vendors may incorporate generative artificial intelligence tools into their offerings without disclosing this use to us, and the providers of these generative artificial intelligence tools may not meet existing or rapidly evolving regulatory or industry standards with respect to privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. If we, our vendors, or our third-party partners experience an actual or perceived breach or privacy or security incident because of the use of generative artificial intelligence, we may lose valuable intellectual property and confidential information and our reputation and the public perception of the effectiveness of our security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of artificial intelligence, to engage in illegal activities involving the theft and misuse of personal information, confidential information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We rely on information technology and data to operate our business of developing product candidates and providing contract research services. Our critical information technology resources include computer networks and hardware, third party hosted services, communications systems and software, and critical data including confidential, personal, proprietary and sensitive data (collectively, "Information Assets"). To operate our business, we also utilize certain third-party service providers to perform a variety of functions, such as professional services, SaaS platforms, managed services, cloud-based infrastructure, encryption and authentication technology, corporate productivity services, and other functions. Accordingly, we have implemented and maintain certain risk assessment processes intended to identify cybersecurity threats, determine their likelihood of occurring, and assess and manage potential material impact to our business. We implement and maintain various information security and risk management processes designed to protect the confidentiality, integrity, and availability of our Information Assets and mitigate harm to our business.

We rely on a multidisciplinary team (including members from information technology ("IT"), which reports to our Chief Financial Officer, finance, and legal, as well as third party service providers as described further below) to identify, assess, and manage cybersecurity threats that could impact our business. We assess the likelihood that such threats could result in a material impact to our Information Assets, operations, ability to provide our services, core business functions, personnel, reputation and identified critical business objectives.

Risks from cybersecurity threats are among those that we address in our general risk management program. We identify, assess, and manage such threats by, among other things, monitoring the threat environment using manual and automated tools, subscribing to reports and services that identify cybersecurity threats, conducting scans of the threat environment, and conducting vulnerability assessments. We also engage third parties to conduct annual penetrations tests, as well as to provide threat and security risk assessments and intelligence feeds.

Based on our assessment process and depending on the environment, we implement and maintain various technical, physical and organizational measures, processes, standards and policies designed to manage and mitigate such risks and potential material impacts. These measures we implement for certain of our Information Assets include: policies and procedures designed to address cybersecurity threats, including an incident response plan; incident detection and response; risk assessments; background checks on our personnel; encryption of data; network security controls; data segregation; access controls; physical security; asset management, tracking and disposal; employee security training; penetration testing; and cyber insurance.

Our assessment and management of material risks from cybersecurity threats are integrated into our overall risk management processes. For example, the IT department works with management to prioritize our risk management processes and mitigate cybersecurity threats that are more likely to lead to a material impact to our business.

We work with third parties from time to time that assist us to identify, assess, and manage material risks from cybersecurity threats, including, for example, professional services firms (including legal counsel), threat intelligence service providers, cybersecurity software providers, managed cybersecurity service providers, forensic investigators, and penetration testing firms.

For a description of the risks from cybersecurity threats that may materially affect us and how they may do so, refer to “Item 1A. Risk factors” in this Annual Report, including “If our information technology systems, those of third parties upon which we rely, or our data are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.”

Governance

Our board of directors, through its Audit Committee, is responsible for overseeing the Company’s risk management strategy with respect to cybersecurity threats. The Audit Committee is responsible for overseeing the Company’s cybersecurity risk management processes, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by certain Company management, including our Chief Financial Officer who is supported by our IT department which includes personnel with experience overseeing and working with various cybersecurity tools. For example, our Senior Director of IT has over 20 years of experience in IT infrastructure and cybersecurity, with extensive expertise in security frameworks, regulatory compliance, and cloud infrastructure management.

Our cybersecurity risk management strategy relies on input from management to help us understand cybersecurity risks, establish priorities, and determine the scope and details of our cybersecurity program and to implement it. Management, including our Chief Financial Officer, is responsible for approving budgets, helping prepare for cybersecurity incidents, approving cybersecurity processes, and reviewing security assessments and other security-related reports. Management, including our Chief Financial Officer and General Counsel, is also responsible for hiring appropriate personnel, engaging third party vendors, integrating cybersecurity considerations into the Company’s overall risk management strategy, approving cybersecurity policies and procedures, and overseeing employee training. Our cybersecurity incident response process involves members of management who also participate in our disclosure controls and procedures.

Our cybersecurity incident response plan and information security incidence response procedures are designed to escalate certain cybersecurity incidents to members of finance and legal, depending on the circumstances, who report to the Chief Financial Officer and the General Counsel. The Chief Financial Officer and the General Counsel work with our cybersecurity incident response team to help us mitigate and remediate cybersecurity incidents of which they are notified. In addition, our cybersecurity incident response plan includes reporting to the Audit Committee for certain cybersecurity incidents.

Members of management meet periodically with the IT department to discuss cybersecurity risk and to review our cybersecurity program, and report to the Audit Committee. The Audit Committee holds meetings biannually to discuss cybersecurity issues including our cybersecurity threats, and has a dedicated agenda during such meetings that is designed to assist the Audit Committee to exercise its oversight function. These meetings involve regular presentations and reports from management and third party providers, including updates of contemporary cybersecurity threats faced by us and steps we are taking to address them.

Item 2. Properties

We lease 11,564 square feet of space for our headquarters in Wayne, Pennsylvania, which we use for our therapeutics business. The lease has a term through February 2029.

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 May 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. 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.

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, 2025, we had 107,918,821 shares of common stock outstanding held by 54 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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required by Item 201(e) of Regulation S-K.

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 on Form 10-K (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 small and large molecule product candidates for immuno-inflammatory diseases. Our proprietary KINect drug discovery platform combined with our preclinical development capabilities allows us to identify and advance potential product candidates that we may develop independently or in collaboration with third parties. In addition to identifying and developing our novel product 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 product candidates. We also provide contract research services to third parties enabled by our early-stage research and development expertise.

Financial Overview

Since our inception, we have incurred significant net losses. Our net loss was \$132.1 million for the year ended December 31, 2024 and \$88.5 million for the year ended December 31, 2023. As of December 31, 2024, we had an accumulated deficit of \$902.9 million. We expect to incur significant expenses and operating losses for the foreseeable future as we advance our product candidates from discovery through preclinical and clinical development. In addition, our product 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 product candidates. Furthermore, we have incurred and expect to continue to incur significant costs associated with operating as a public company, including legal, accounting, investor relations and other expenses. As a result, we will need substantial additional funding to support our continuing operations.

We have historically financed our operations primarily with sales of equity securities and incurring indebtedness in the form of loans from commercial lenders. In the near term, we expect to finance our operations through these and other capital sources, including potential partnerships with other companies or other strategic transactions. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on commercially acceptable terms, or at all. If we fail to raise capital or enter into such agreements as, and when needed, we may have to significantly delay, scale back or discontinue the development of one or more of our product candidates.

Impact of Macroeconomic Conditions on Our Business

Unfavorable conditions in the economy both in the United States and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, including inflationary pressure and geopolitical conflicts, have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed. For further discussion of the potential impacts of macroeconomic events on our business, financial condition, and operating results, see the section titled “Risk Factors.”

Acquisition and License Agreements

Exclusive License Agreement with Biosion

In November 2024, we entered into an exclusive license agreement (the “Biosion Agreement”) with Biosion, Inc. (“Biosion”) pursuant to which we received the exclusive rights to develop, manufacture and commercialize bosakitug

(ATI-045) and ATI-052 worldwide, excluding Mainland China, Macau, Hong Kong and Taiwan (“Greater China”). In connection with the Biosion Agreement, we also entered into a collaboration agreement (the “CTTQ Agreement”) with Biosion and Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (“CTTQ”), a licensee of bosakitug in Greater China.

As partial consideration for the rights and licenses under the Biosion Agreement and CTTQ Agreement, we agreed to, in the aggregate, (i) pay \$30.0 million in upfront cash consideration, plus \$4.5 million for the reimbursement of certain development costs, (ii) issue warrants (the “Warrants”) to purchase 14,281,985 shares of our common stock and (iii) pay \$6.2 million for the reimbursement of certain development costs and drug product material as set forth in the Biosion Agreement. We determined that the transaction was an acquisition of assets with no alternative future use and therefore expensed as incurred the fair value of the consideration given of \$85.6 million as a component of in-process research and development expense during the year ended December 31, 2024. We incurred \$1.3 million in expenses related to this transaction which were expensed as incurred.

In addition, we agreed to pay, in the aggregate, (i) up to \$125 million upon the achievement of specified regulatory milestones commencing with product approval, (ii) up to \$795 million upon the achievement of specified sales milestones, (iii) a tiered low-to-mid single digit royalty based upon a percentage of annual net sales, subject to specified reductions as set forth in the Biosion Agreement, and (iv) a portion of any sublicense consideration received from the grant of any sublicense or similar rights under any of the rights or licenses granted to us under the Biosion Agreement. We will expense these payments in the period when either they are determined to be probable of occurring or when the payment is triggered.

The Warrants have an initial exercise price of \$0.00001 per share, subject to adjustment as provided in the Warrants. The Warrants are immediately exercisable, subject to any applicable overseas direct investment filing that may be required for the holders. The Warrants will terminate when exercised in full. We classified the Warrants within equity because they are indexed to our own stock. We assigned an estimated fair value of \$44.8 million to the Warrants, which was based on the fair value of our common stock on the date of issuance less the nominal exercise price of \$0.00001 per share.

Royalty Purchase Agreement with OCM IP Healthcare Portfolio LP

In July 2024, we entered into a royalty purchase agreement with OCM IP Healthcare Portfolio LP, an investment vehicle for Ontario Municipal Employees Retirement System (“OMERS”). Under the royalty purchase agreement, we sold to OMERS a portion of the future royalty payments and the remaining anniversary milestones associated with our existing license to Eli Lilly and Company (“Lilly”), relating to OLUMIANT® (baricitinib) for the treatment of alopecia areata (see “—License Agreement with Eli Lilly and Company”). Under the terms of the royalty purchase agreement, we received an upfront payment of \$26.5 million. In exchange, OMERS acquired a portion of the royalty payable by Lilly to us for worldwide net sales of OLUMIANT for the treatment of alopecia areata from April 1, 2024 through the remainder of the royalty term under our license agreement with Lilly, and 100% of the remaining anniversary milestone payments payable by Lilly to us under the license agreement. The royalty payments and milestones we sold to OMERS represent our entire financial interest in the Lilly license agreement after taking into account our other contractual third-party obligations.

We recognized \$1.9 million of non-cash royalty income during the year ended December 31, 2024.

License Agreement with Sun Pharmaceutical Industries, Inc.

In December 2023, we entered into an exclusive patent license agreement with Sun Pharmaceutical Industries, Inc. (“Sun Pharma”). Under the license agreement, we granted Sun Pharma exclusive rights under certain patents that we exclusively license from a third party. The patents relate to the use of deuruxolitinib, Sun Pharma’s JAK inhibitor, or other isotopic forms of ruxolitinib, to treat alopecia areata or androgenetic alopecia. Under the license agreement, Sun Pharma has paid us an upfront payment and certain regulatory payments, and has agreed to pay us other regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a mid single-digit tiered royalty calculated as a percentage of Sun Pharma’s net sales. We have separate contractual obligations under which we have agreed to pay to third parties a portion of the consideration we may receive under the license agreement.

We recognized \$3.0 million and \$15.0 million of licensing revenue during the years ended December 31, 2024 and 2023, respectively.

License Agreement with Pediatrix Therapeutics, Inc.

In November 2022, we entered into a license agreement with Pediatrix Therapeutics, Inc. (“Pediatrix”) under which we granted Pediatrix the exclusive rights to develop, manufacture and commercialize lepzacitinib in Greater China. Pediatrix has paid us an upfront payment, and has agreed to pay us development, regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a tiered royalty ranging from a low-to-high single digit percentage of net sales of lepzacitinib by Pediatrix in Greater China. A portion of the consideration received from Pediatrix is payable to the former Confluence equity holders as described below under the caption “—Agreement and Plan of Merger with Confluence.”

License Agreement with Eli Lilly and Company

In August 2022, we entered into a non-exclusive patent license agreement with Lilly. Under the license agreement, we granted Lilly non-exclusive rights under certain patents and patent applications that we exclusively license from a third party. The patents and patent applications relate to the use of baricitinib, Lilly’s JAK inhibitor, to treat alopecia areata. Under the license agreement, Lilly has paid us an upfront payment and regulatory and certain commercial milestone payments, and agreed to pay us anniversary payments and other commercial milestone payments upon the achievement of specified milestones as set forth in the agreement, and a low single-digit royalty calculated as a percentage of Lilly’s net sales of baricitinib for the treatment of alopecia areata. We have separate contractual obligations under which we have agreed to pay to third parties an amount equal to any regulatory and commercial milestone payments we receive under the Lilly license agreement, as well as a portion of the upfront consideration and a portion of the royalties we may receive under the license agreement. In July 2024, we entered into a royalty purchase agreement with OMERS pursuant to which we sold to OMERS a portion of our future royalty payments and the remaining anniversary milestones associated with the license to Lilly (see “—Royalty Purchase Agreement with OCM IP Healthcare Portfolio LP” above).

We recognized \$13.2 million and \$12.7 million of licensing revenue during the years ended December 31, 2024 and 2023, respectively.

Asset Purchase Agreement with EPI Health, LLC

In October 2019, we sold RHOFADÉ (oxymetazoline hydrochloride) cream, 1% (“RHOFADÉ”) to EPI Health, LLC (“EPI Health”) pursuant to an asset purchase agreement. In July 2023, EPI Health filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code. Through the bankruptcy process, EPI Health and its parent company, Novan, Inc., sold the RHOFADÉ assets to a third party, which excluded our asset purchase agreement with EPI Health and the outstanding amounts due. The sale was approved by the bankruptcy court in September 2023. As a result of the bankruptcy proceedings, all amounts that were due and outstanding by EPI Health have been fully reserved.

Agreement and Plan of Merger with Confluence

In 2017, we entered into an Agreement and Plan of Merger (the “Confluence Agreement”) with Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) (“Confluence”), Aclaris Life Sciences, Inc., our wholly-owned subsidiary (“Merger Sub”), and Fortis Advisors LLC, as representative of the equity holders of Confluence. Pursuant to the terms of the Confluence Agreement, Merger Sub merged with and into Confluence, with Confluence surviving as our wholly-owned subsidiary.

Under the Confluence Agreement, we have 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.

Discontinued Programs

We were previously developing zunsemetinib (ATI-450) as a potential treatment for various immuno-inflammatory diseases, including hidradenitis suppurativa, psoriatic arthritis, and rheumatoid arthritis. Following the results of the Phase 2 trials for these programs, we discontinued further development of our mitogen-activated protein kinase-activated protein kinase 2 (“MK2”) inhibitor programs in immuno-inflammatory diseases in 2023.

We were also previously exploring the use of ATI-2231, our second MK2 inhibitor, as a potential treatment for oncology diseases, but decided to pursue this with zunsemetinib due to its more advanced clinical development package.

Restructuring

In December 2023, our board of directors approved a reduction of our workforce by approximately 46%, which was completed as of December 31, 2024. For the year ended December 31, 2024, we incurred severance expenses of \$2.7 million and made cash severance payments of \$5.6 million to impacted employees. In the year ended December 31, 2023, we recorded a restructuring charge of \$3.1 million, representing one-time termination benefits for employees with retention periods less than the sixty-day minimum retention period.

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.

Licensing

Licensing revenue primarily consists of upfront consideration, royalties and milestone payments earned pursuant to license and acquisition agreements with third parties, as described above.

Cost and Expenses

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

Research and development expenses consist of expenses incurred in connection with the discovery and development of our product candidates. These expenses primarily include:

- expenses incurred under agreements with contract research organizations (“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, including domestic technology transfer expenses;
- quality assurance and quality control costs;

- outsourced professional scientific development services;
- medical affairs expenses related to our product candidates;
- employee-related expenses, which include salaries, benefits and stock-based compensation;
- 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. Product 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 development of our product candidates and pursue our discovery programs. 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 product 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 product candidates. This uncertainty is due to the numerous risks and uncertainties associated with the duration and cost of discovery, as well as clinical trials, which vary significantly over the life of a project as a result of many factors, including:

- the number of clinical sites included in the trials;
- the length of time required to enroll suitable subjects;
- the number of subjects that ultimately participate in the trials;
- the number of doses subjects receive;
- the duration of subject follow-up; and
- the results of our clinical trials.

Our expenditures are subject to additional uncertainties, including the preparation of regulatory filings for our product 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 product candidates or focus on others. A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product 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

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, business development costs, insurance costs and travel expenses.

Licensing

Licensing expenses consist of third-party contractual obligations incurred under license and acquisition agreements with third parties, as described above.

Revaluation of Contingent Consideration

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

In-process Research and Development

In-process research and development (“IPR&D”) consists of expenses related to in-licensed assets with no future alternative use and impairment charges recorded for IPR&D intangible assets.

Other Income

Interest Income

Interest income primarily consists of interest earned on our cash, cash equivalents and marketable securities.

Non-cash Royalty Income

In July 2024, we entered into the royalty purchase agreement with OMERS pursuant to which we sold a portion of our royalties due to us under the license agreement with Lilly and received upfront proceeds of \$26.5 million.

We evaluated the royalty purchase agreement under Accounting Standards Codification (“ASC”) 470 – Debt and concluded that the upfront payment should be accounted for as deferred income because the criteria for debt classification were not met. We apply the “units-of-revenue” method of recognizing income in the consolidated statements of operations and comprehensive loss and such amounts are included in non-cash royalty income.

Critical Accounting Estimates

This discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements which have been 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, the 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 or 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, 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.

Contingent Consideration

We record a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of 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 is 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. These assumptions are highly dependent on the outcome and timing of the development of certain of our product candidates. 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 17% and 40% at December 31, 2024. 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 7.4% and 8.7% depending on the year of each potential payment.

During the year ended December 31, 2024, we adjusted estimated sales and the probability of success for certain product candidates. These changes, as well as the passage of time, partially offset by higher discount rates resulting from higher risk-free rates and changes in credit spreads, resulted in an overall increase of \$2.5 million during the year ended December 31, 2024.

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 (“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 our stock price’s historical volatility, as we have determined that 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.

Results of Operations

Comparison of Years Ended December 31, 2024 and 2023

(In thousands)	Year Ended December 31,		Change
	2024	2023	
Revenues:			
Contract research	\$ 2,541	\$ 3,035	\$ (494)
Licensing	16,179	28,214	(12,035)
Total revenue	18,720	31,249	(12,529)
Costs and expenses:			
Cost of revenue	2,792	3,423	(631)
Research and development	33,586	98,384	(64,798)
General and administrative	22,203	32,412	(10,209)
Licensing	12,666	14,658	(1,992)
Revaluation of contingent consideration	2,500	(26,900)	29,400
In-process research and development	86,905	6,629	80,276
Total costs and expenses	160,652	128,606	32,046
Loss from operations	(141,932)	(97,357)	(44,575)
Other income:			
Interest income	7,953	8,509	(556)
Non-cash royalty income	1,914	—	1,914
Total other income	9,867	8,509	1,358
Loss before income taxes	(132,065)	(88,848)	(43,217)
Income tax benefit	—	(367)	367
Net loss	<u>\$ (132,065)</u>	<u>\$ (88,481)</u>	<u>\$ (43,584)</u>

Revenue

Contract Research

Contract research revenue was \$2.5 million and \$3.0 million for the years ended December 31, 2024 and 2023, respectively, and was comprised of fees earned from the provision of laboratory services to our clients. The decrease was driven by lower overall hours billed, which was offset by a higher average billing rate.

Licensing

Licensing revenue was \$16.2 million and \$28.2 million for the years ended December 31, 2024 and 2023, respectively. The decrease was primarily driven by the upfront payment received under the Sun Pharma agreement during the year ended December 31, 2023, partially offset by the achievement of higher milestones under license agreements during the year ended December 31, 2024.

Cost and Expenses

Cost of Revenue

Cost of revenue was \$2.8 million and \$3.4 million for the years ended December 31, 2024 and 2023, respectively, and in each case related to providing laboratory services to our clients. Changes in cost of revenue generally correlate to changes in contract research revenue. Cost of revenue decreased during the year ended December 31, 2024 due to lower variable costs resulting from a decrease in hours billed, which was offset by an increase in termination benefits as a result of our restructuring that was announced in December 2023.

Research and Development

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

(In thousands)	Year Ended December 31,		Change
	2024	2023	
Bosakitug	\$ 299	\$ —	\$ 299
ATI-2138	4,209	12,143	(7,934)
ATI-052	1,895	—	1,895
Lepzacitinib	1,300	12,129	(10,829)
Zunsemetinib	4,496	36,461	(31,965)
Discovery	5,775	6,881	(1,106)
Other research and development	1,031	4,992	(3,961)
Personnel	11,446	18,977	(7,531)
Stock-based compensation	3,135	6,801	(3,666)
Total research and development expenses	<u>\$ 33,586</u>	<u>\$ 98,384</u>	<u>\$ (64,798)</u>

ATI-2138

The decrease in expenses for ATI-2138 during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to a decrease in clinical development expenses associated with a Phase 1 MAD trial which was completed in September 2023, as well as a decrease in preclinical development activities. This decrease was partially offset by clinical development expenses associated with a Phase 2a trial that was initiated in August 2024.

ATI-052

Research and development expenses related to ATI-052 for the year ended December 31, 2024 primarily consisted of product candidate manufacturing costs and preclinical development activities. Because we in-licensed ATI-052 in 2024, there were no related expenses for the year ended December 31, 2023.

Lepzacitinib

The decrease in expenses for lepzacitinib during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to lower costs associated with preclinical development activities and costs associated with a Phase 2b clinical trial in subjects with atopic dermatitis, which was initiated in May 2022 and was completed in January 2024.

Zunsemetinib

The decrease in expenses for zunsemetinib during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to a decrease in costs associated with Phase 2 clinical development activities which were completed in 2023 as well as a decrease in product manufacturing costs.

Personnel and stock-based compensation

The decrease in personnel and stock-based compensation expenses during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to lower headcount, lower termination benefits and higher forfeiture credits as a result of our restructuring that was announced in December 2023.

General and Administrative

The following table summarizes our general and administrative expenses:

(In thousands)	Year Ended December 31,		Change
	2024	2023	
Personnel	\$ 6,786	\$ 8,016	\$ (1,230)
Professional and legal fees	4,508	5,534	(1,026)
Facility and support services	2,234	3,023	(789)
Other general and administrative	1,892	2,240	(348)
Stock-based compensation	6,783	12,285	(5,502)
Bad debt	—	1,314	(1,314)
Total general and administrative expenses	\$ 22,203	\$ 32,412	\$ (10,209)

Personnel and stock-based compensation

The aggregate decrease in personnel and stock-based compensation expenses during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily due to lower headcount and higher forfeiture credits.

Professional and legal fees

The decrease in professional and legal fees, including accounting, investor relations and corporate communication costs, during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily driven by a decrease in accounting related expenses, which were partially offset by an increase in business development expenses.

Facility and support services

The decrease in facility and support services, including general office expenses, information technology costs and other expenses, during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily driven by a decrease in rent expense and information technology expenses.

Bad debt

Bad debt expenses were related to our determination that amounts due to us as of December 31, 2023 pursuant to the asset purchase agreement with EPI Health are uncertain as a result of the bankruptcy filing by EPI Health in July 2023. There was no bad debt expense during the year ended December 31, 2024.

Licensing

The decrease in licensing expenses during the year ended December 31, 2024 compared to the year ended December 31, 2023 was primarily driven by the upfront payment received under the Sun Pharma agreement during the year ended December 31, 2023, a portion of which was payable to third parties, partially offset by the achievement of higher milestones under license agreements during the year ended December 31, 2024.

Revaluation of Contingent Consideration

The revaluation of contingent consideration loss during the year ended December 31, 2024 was primarily due to changes in estimated sales levels and changes to the probability of success for certain product candidates, compared to the revaluation of contingent consideration gain during the year ended December 31, 2023 which was primarily due to the removal of estimated sales levels of zunsemetinib following our decision to discontinue further development of our MK2 inhibitor programs in immuno-inflammatory diseases.

In-process Research and Development

In-process research and development expenses recorded during the year ended December 31, 2024 included the fair value of the consideration expensed in connection with the in-license of bosakitug and ATI-052, as well as transaction costs incurred as part of the transaction. During the quarter ended December 31, 2023, we performed an impairment analysis on the IPR&D intangible asset acquired from Confluence due to our decision to discontinue further development of the product candidate for immuno-inflammatory diseases. Our impairment analysis resulted in a fair value of the IPR&D intangible asset which was less than the carrying value and as a result, we recorded an impairment charge for the full balance of the IPR&D intangible asset during the year ended December 31, 2023.

Other Income

Interest Income

Interest income decreased during the year ended December 31, 2024 compared to the year ended December 31, 2023 primarily due to lower interest income on investment portfolio balances.

Non-cash Royalty Income

Non-cash royalty income includes income related to the proceeds from the sale of future royalties to OMERS, recognized under the “units-of-revenue” method.

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, 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 third-party licensing and acquisition agreements. 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 product candidates, we may receive upfront payments, milestone payments or royalties from such arrangements that would increase our liquidity.

As of December 31, 2024, we had cash, cash equivalents and marketable securities of \$203.9 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, Biosion Agreement and CTTQ Agreement, which are summarized above under “Overview—Acquisition and License Agreements,” and our lease obligations.

Equity Financing

Private Placement

In November 2024, we closed a private placement in which we sold 35.6 million shares of our common stock for aggregate gross proceeds of \$80.0 million. We paid placement agent and other fees of \$5.1 million in connection with the private placement.

At-the-Market Facility

In April 2023, we sold 3.4 million shares of our common stock for aggregate gross proceeds of \$27.5 million, pursuant to a sales agreement with Leerink Partners LLC (formerly SVB Securities LLC) and Cantor Fitzgerald & Co., as sales agents, dated February 23, 2023. We paid selling commissions of \$0.8 million in connection with the sale.

Cash Flows

Cash and cash equivalents were \$24.6 million as of December 31, 2024 compared to \$39.9 million as of December 31, 2023. We also had \$179.3 million in short- and long-term marketable securities as of December 31, 2024 compared to \$142.0 million as of December 31, 2023.

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

(In thousands)	Year Ended December 31,	
	2024	2023
Cash and cash equivalents beginning balance	\$ 39,878	\$ 45,277
Net cash used in operating activities	(20,075)	(78,325)
Net cash (used in) provided by investing activities	(69,769)	46,220
Net cash provided by financing activities	74,536	26,706
Cash and cash equivalents ending balance	<u>\$ 24,570</u>	<u>\$ 39,878</u>

Operating Activities

Cash flow related to operating activities was the result of:

(In thousands)	Year Ended December 31,	
	2024	2023
Net loss	\$ (132,065)	\$ (88,481)
Non-cash adjustments to reconcile net loss to net cash used in operating activities	101,068	767
Change in accounts receivable	(20)	186
Change in prepaid expenses and other assets	(4,855)	(1,315)
Change in accounts payable and accrued expenses	(8,130)	10,518
Change in deferred income	23,927	—
Net cash used in operating activities	<u>\$ (20,075)</u>	<u>\$ (78,325)</u>

Net cash used in operating activities decreased for the year ended December 31, 2024 compared to the year ended December 31, 2023 primarily as a result of lower net losses after adjusting for non-cash items and proceeds from the royalty sale to OMERS. The change was partially offset by an increase in cash used for accounts payable and accrued expenses, which was due to the timing of payments to vendors and severance payments as a result of our restructuring announced in December 2023.

The increase in non-cash adjustments to reconcile net loss to net cash used in operating activities was mainly the result of in-process research and development expenses recorded in connection with the in-license of bosakitug and ATI-052.

Investing Activities

Cash flow related to investing activities was the result of:

(In thousands)	Year Ended December 31,	
	2024	2023
Purchases of property and equipment, net	\$ (121)	\$ (1,309)
Purchases of marketable securities	(119,982)	(135,675)
Proceeds from sales and maturities of marketable securities	86,144	183,204
Acquisition of in-licensed assets, including transaction costs	(35,810)	—
Net cash (used in) provided by investing activities	<u>\$ (69,769)</u>	<u>\$ 46,220</u>

Net cash used in investing activities for the year ended December 31, 2024 was \$69.8 million compared to net cash provided by investing activities during the year ended December 31, 2023 of \$46.2 million. The change was primarily

due to the consideration paid for the acquisition of in-licensed assets in connection with the Biosion Agreement and CTTQ Agreement and lower sales and maturities of marketable securities, partially offset by a reduction in purchases of marketable securities.

Financing Activities

Cash flow related to financing activities was the result of:

(In thousands)	Year Ended December 31,	
	2024	2023
Proceeds from issuance of common stock under securities purchase agreement, net of issuance costs	\$ 74,913	\$ —
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	26,714
Payments of employee withholding taxes related to restricted stock unit award vesting and exercise of employee stock options	(409)	(102)
Proceeds from exercise of employee stock options and the issuance of stock	32	94
Net cash provided by financing activities	<u>\$ 74,536</u>	<u>\$ 26,706</u>

The increase in net cash provided by financing activities for the year ended December 31, 2024 compared to December 31, 2023 was primarily due to proceeds from our private placement in November 2024, offset by proceeds from sales under our at-the-market sales agreement in 2023.

Funding Requirements

We anticipate we will incur net losses in the near term as we continue the development of our product candidates and continue to discover and develop additional product 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 product 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 product candidates.

Our primary uses of capital are, and we expect will continue to be, compensation and related expenses, research and development expenses, laboratory and related supplies, legal and other regulatory expenses, and administrative and overhead costs. Our future funding requirements will be heavily determined by the resources needed to support the development of our product candidates, without taking into account any potential business development activities.

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 based on our current operating assumptions. We will require additional capital to develop our product candidates 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 caused by a variety of factors including geopolitical tensions and inflationary pressures. 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 product 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 product candidates, 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 product candidates that we may pursue;
- the scope, progress, results and costs of preclinical development, laboratory testing and conducting preclinical and clinical trials for our product candidates;
- the costs, timing and outcome of regulatory review of our product candidates;
- the extent to which we in-license or acquire additional product candidates and technologies;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims;
- our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product 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 lease agreement which has a term through February 2029. We also occupy office and laboratory space in St. Louis, Missouri under a sublease agreement which has a term through May 2029.

Our aggregate remaining lease payment obligation for these two spaces was \$3.2 million as of December 31, 2024.

Agreement and Plan of Merger with 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.

Exclusive License Agreement with Biosion; Collaboration Agreement with Biosion and CTTQ

Under the Biosion and CTTQ Agreements, we agreed to pay, in the aggregate, up to \$920 million upon the achievement of specified regulatory and sales milestones. In addition, we have agreed to pay future royalty payments calculated as a low-to-mid single digit percentage of annual net sales, subject to specified reductions, as set forth in the Biosion Agreement. In addition to the payments described above, we have also agreed to pay a portion of any sublicense consideration received from the grant of any sublicense or similar rights under any of the rights or licenses granted to us under the Biosion Agreement.

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 2024, the Financial Accounting Standards Board (“FASB”) issued Accounting Standards Update (“ASU”) No. 2024-03, “Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.” This standard requires disclosure of additional information about specific expense categories in the notes to financial statements on an annual and interim basis. This ASU becomes effective for annual periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027. We are currently assessing the impact of this ASU.

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes (Topic 740): Improvements to Income Tax Disclosures.” This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. This ASU becomes effective for annual periods beginning after December 15, 2024. We are currently assessing the impact of this ASU.

In November 2023, the FASB issued ASU No. 2023-07, “Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.” This standard requires disclosure of significant segment expenses and other segment items by reportable segment. We adopted ASU No. 2023-07 effective December 31, 2024, on a retrospective basis, the impact of which is limited to additional segment expense disclosures in the notes to our consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information under this item.

Item 8. Financial Statements and Supplementary Data

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Aclaris Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aclaris Therapeutics, Inc. and its subsidiaries (the “Company”) as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of stockholders’ equity and of cash flows for the years then ended, including the related notes (collectively referred to as the “consolidated financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

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

Critical Audit Matters

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

Fair Value of the Contingent Consideration Liability

As described in Notes 2 and 3 to the consolidated financial statements, the Company’s contingent consideration balance was \$8.7 million as of December 31, 2024. The Company records a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of 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. 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 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, 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 27, 2025

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, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 24,570	\$ 39,878
Short-term marketable securities	89,024	79,228
Accounts receivable, net	318	298
Prepaid expenses and other current assets	12,039	9,452
Total current assets	125,951	128,856
Marketable securities	90,302	62,771
Property and equipment, net	1,008	1,620
Other assets	3,066	4,158
Total assets	<u>\$ 220,327</u>	<u>\$ 197,405</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 4,690	\$ 8,878
Accrued expenses	20,333	19,446
Deferred income	3,890	—
Other current liabilities	2,683	2,628
Total current liabilities	31,596	30,952
Other liabilities	4,439	3,074
Deferred income, net of current portion	20,038	—
Contingent consideration	8,700	6,200
Total liabilities	64,773	40,226
Stockholders' Equity:		
Preferred stock, \$0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at December 31, 2024 and December 31, 2023	—	—
Common stock, \$0.00001 par value; 200,000,000 shares authorized at December 31, 2024 and December 31, 2023; 107,850,124 and 70,894,889 shares issued and outstanding at December 31, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	1,058,317	928,080
Accumulated other comprehensive income (loss)	97	(106)
Accumulated deficit	(902,861)	(770,796)
Total stockholders' equity	155,554	157,179
Total liabilities and stockholders' equity	<u>\$ 220,327</u>	<u>\$ 197,405</u>

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

ACLARIS THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(In thousands, except share and per share data)

	Year Ended December 31,	
	2024	2023
Revenues:		
Contract research	\$ 2,541	\$ 3,035
Licensing	16,179	28,214
Total revenue	18,720	31,249
Costs and expenses:		
Cost of revenue	2,792	3,423
Research and development	33,586	98,384
General and administrative	22,203	32,412
Licensing	12,666	14,658
Revaluation of contingent consideration	2,500	(26,900)
In-process research and development	86,905	6,629
Total costs and expenses	160,652	128,606
Loss from operations	(141,932)	(97,357)
Other income:		
Interest income	7,953	8,509
Non-cash royalty income	1,914	—
Total other income	9,867	8,509
Loss before income taxes	(132,065)	(88,848)
Income tax benefit	—	(367)
Net loss	\$ (132,065)	\$ (88,481)
Net loss per share, basic and diluted	\$ (1.71)	\$ (1.27)
Weighted average common shares outstanding, basic and diluted	77,296,665	69,808,855
Other comprehensive income:		
Unrealized gain on marketable securities, net of tax of \$0	\$ 203	\$ 791
Total other comprehensive income	203	791
Comprehensive loss	\$ (131,862)	\$ (87,690)

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 Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Par Value				
Balance at December 31, 2022	66,688,647	\$ 1	\$ 880,832	\$ (897)	\$ (682,315)	\$ 197,621
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	806,242	—	(8)	—	—	(8)
Issuance of common stock under at-the-market sales agreement, net of offering costs of \$826	3,400,000	—	26,714	—	—	26,714
Unrealized gain on marketable securities	—	—	—	791	—	791
Stock-based compensation expense	—	—	20,542	—	—	20,542
Net loss	—	—	—	—	(88,481)	(88,481)
Balance at December 31, 2023	70,894,889	\$ 1	\$ 928,080	\$ (106)	\$ (770,796)	\$ 157,179
Issuance of common stock in connection with exercise of stock options and vesting of restricted stock units	1,399,680	—	(377)	—	—	(377)
Issuance of common stock under securities purchase agreement, net of offering costs of \$5,087	35,555,555	—	74,913	—	—	74,913
Issuance of common stock purchase warrants	—	—	44,845	—	—	44,845
Unrealized gain on marketable securities	—	—	—	203	—	203
Stock-based compensation expense	—	—	10,856	—	—	10,856
Net loss	—	—	—	—	(132,065)	(132,065)
Balance at December 31, 2024	107,850,124	\$ 1	\$ 1,058,317	\$ 97	\$ (902,861)	\$ 155,554

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (132,065)	\$ (88,481)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	807	863
Stock-based compensation expense	10,856	20,542
Revaluation of contingent consideration	2,500	(26,900)
In-process research and development expense	86,905	6,629
Deferred taxes	—	(367)
Changes in operating assets and liabilities:		
Accounts receivable	(20)	186
Prepaid expenses and other assets	(4,855)	(1,315)
Accounts payable	(4,188)	(1,473)
Accrued expenses and other liabilities	(3,942)	11,991
Deferred income	23,927	—
Net cash used in operating activities	<u>(20,075)</u>	<u>(78,325)</u>
Cash flows from investing activities:		
Purchases of property and equipment, net	(121)	(1,309)
Purchases of marketable securities	(119,982)	(135,675)
Proceeds from sales and maturities of marketable securities	86,144	183,204
Acquisition of in-licensed assets, including transaction costs	(35,810)	—
Net cash (used in) provided by investing activities	<u>(69,769)</u>	<u>46,220</u>
Cash flows from financing activities:		
Proceeds from issuance of common stock under securities purchase agreement, net of issuance costs	74,913	—
Proceeds from issuance of common stock under the at-the-market sales agreement, net of issuance costs	—	26,714
Payments of employee withholding taxes related to restricted stock unit award vesting and exercise of employee stock options	(409)	(102)
Proceeds from exercise of employee stock options and the issuance of stock	32	94
Net cash provided by financing activities	<u>74,536</u>	<u>26,706</u>
Net decrease in cash and cash equivalents	<u>(15,308)</u>	<u>(5,399)</u>
Cash and cash equivalents at beginning of period	<u>39,878</u>	<u>45,277</u>
Cash and cash equivalents at end of period	<u>\$ 24,570</u>	<u>\$ 39,878</u>
Supplemental disclosure of non-cash investing and financing activities:		
Fair value of warrants issued in connection with in-license agreement	\$ 44,845	\$ —
Deferred transaction consideration in connection with in-license agreement	6,249	—

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. Aclaris Therapeutics, Inc. and its wholly owned subsidiaries are referred to collectively as the “Company.”

The Company is a clinical-stage biopharmaceutical company focused on developing novel small and large molecule product candidates for immuno-inflammatory diseases. The Company’s proprietary KINect drug discovery platform combined with its preclinical development capabilities allows the Company to identify and advance potential product candidates that it may develop independently or in collaboration with third parties. In addition to identifying and developing its novel product 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 product candidates. The Company also provides contract research services to third parties enabled by its early-stage research and development expertise.

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, 2024, the Company had cash, cash equivalents and marketable securities of \$203.9 million and an accumulated deficit of \$902.9 million. Since inception, the Company has incurred net losses and negative cash flows from its operations. 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 product candidates, will require significant additional financing. The future viability of the Company is dependent on its ability to successfully develop its product 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 develop its product candidates 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 potentially worsening global economic conditions caused by a variety of factors including geopolitical tensions and inflationary pressures. 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 product 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 Codification (“ASC”) Subtopic 205-40, Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern, 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. 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.

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. 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 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 Revenue

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.

Licensing Revenue

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

Milestone and Royalty Payments – The Company considers any future potential milestones and sales-based royalties to be variable consideration. The Company recognizes revenue from development, regulatory and

anniversary milestone payments as they are achieved. The Company recognizes revenue from commercial milestones and royalty payments as the sales occur.

Deferred Income Related to the Sale of Future Royalties

The Company amortizes its deferred income liability related to the sale of future OLUMIANT® (baricitinib) royalties under the units-of-revenue method by computing a ratio of the proceeds received to the total expected payments over the term of the royalty purchase agreement and then applying that ratio to the period's estimated cash payment (see Note 13). The amortization is based on the Company's current estimate of future royalty payments.

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 funds 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 marketable securities as available-for-sale securities. The Company's marketable securities are measured and reported at fair value using either quoted prices in active markets for identical securities or quoted prices in markets that are not active for identical or similar securities. Unrealized gains and losses are reported as a separate component of stockholders' equity. The cost of securities sold is determined on a specific identification basis, and realized gains and losses, if any, are included in other income 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 three to five years. Furniture and fixtures are depreciated over five years. Leasehold improvements are depreciated over the shorter of the lease term or their useful life. Expenditures for repairs and maintenance of assets are charged to expense as incurred. Upon retirement or sale, the cost and related accumulated depreciation of assets disposed of are removed from the accounts and any resulting gain or loss is included in loss from operations.

Impairment of Long-Lived Assets

Long-lived assets consist of property and equipment. Long-lived assets to be held and used are tested for recoverability whenever events or changes in business circumstances indicate that the carrying amount of the assets may not be fully recoverable. Factors that the Company considers in deciding when to perform an impairment review include significant underperformance of the business in relation to expectations, significant negative industry or economic trends and significant changes or planned changes in the use of the assets. If an impairment review is performed to evaluate a long-lived asset for recoverability, the Company compares forecasts of undiscounted cash flows expected to result from the use and eventual disposition of the long-lived asset to its carrying value. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset over its fair value, determined based on discounted cash flows.

Intangible Assets

Intangible assets include both definite-lived and indefinite-lived assets. Definite-lived intangible assets consist of

a drug discovery platform the Company acquired through the acquisition of Confluence Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) (“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 consisted of an in-process research and development (“IPR&D”) product 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 product candidate is approved and launched commercially, or expensed immediately if development of the product 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 quarter ended December 31, 2023, the Company performed an impairment analysis on the IPR&D intangible asset due to the Company’s decision to discontinue further development of the product candidate in immuno-inflammatory diseases. The Company’s impairment analysis resulted in a fair value of the IPR&D intangible asset which was less than the carrying value. As a result, the Company recorded an impairment charge of \$6.6 million, the full balance of the IPR&D intangible asset.

Discontinued Operations

As of December 31, 2024 and 2023, the Company had \$2.2 million in discontinued operations reported as other current liabilities in the Company’s consolidated balance sheet, related to discontinued commercial products.

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 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 leases on a straight-line basis over the term of each lease. 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 on the Company’s consolidated balance sheet for operating leases. Obligations for lease payments are included in other current liabilities and other liabilities on the Company’s consolidated balance sheet for operating leases.

Contingent Consideration

The Company records a contingent consideration liability related to future potential payments resulting from the acquisition of Confluence based upon significant unobservable inputs including the achievement of 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 is 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 17% and 40% at December 31, 2024. 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 7.4% and 8.7% 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, 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.

Acquisitions

In November 2024, the Company entered into an exclusive license agreement with Biosion, Inc. ("Biosion") (as described in Note 12). This transaction has been accounted for as an asset acquisition in accordance with the Financial Accounting Standards Board ("FASB") ASC 805-50, rather than a business combination. Cash payments and issuances of equity instruments for IPR&D, as well as future payments, are initially treated as the acquisition of an asset but then immediately expensed as there is no future alternative use under the accounting guidance for the asset. These payments are reflected as IPR&D expense on the Company's consolidated statements of operations and comprehensive loss.

The Company accounted for the transaction as an asset acquisition because substantially all of the fair value of the assets acquired is concentrated in a single asset. ASC 805-10-55-5A, which sets forth a screen test, provides that if substantially all of the fair value of assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets, the assets acquired are not a business.

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, which is typically four years. 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 expected volatility based on its stock price's historical volatility, as the Company has determined that 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 and 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 the assumed vesting of RSUs, if dilutive. Since the Company was in a net loss position, basic and diluted net loss per share were the same for each of the periods presented.

Fair Value Measurements

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

- Level 1 — Quoted prices in active markets for identical assets or liabilities.
- Level 2 — Observable inputs (other than Level 1 quoted prices), such as quoted prices in active markets for similar assets or liabilities, quoted prices in markets that are not active for identical or similar assets or liabilities, or other inputs that are observable or can be corroborated by observable market data.
- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to determining the fair value of the assets or liabilities, including pricing models, discounted cash flow methodologies and similar techniques.

The Company's cash equivalents, marketable securities and contingent consideration are carried at fair value, determined according to the fair value hierarchy described above. The carrying value of the Company's accounts payable and accrued expenses approximate fair value due to the short-term nature of these liabilities.

Concentration of Credit Risk and of Significant Suppliers

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company holds all cash, cash equivalents and marketable securities balances at three accredited financial institutions, the majority of which are in amounts that exceed or are not subject to 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 ("CODM") 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. The Company does not report asset information by segment because it is not regularly provided to the CODM, and all of the Company's assets are held in the United States.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued Accounting Standards Update ("ASU") No. 2024-03, "Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses." This standard requires disclosure of additional information about specific expense categories in the notes to financial statements on an annual and interim basis. This ASU becomes effective for annual periods beginning after December 15, 2026 and interim periods within annual reporting periods beginning after December 15, 2027. The Company is currently assessing the impact of this ASU.

In December 2023, the FASB issued ASU No. 2023-09, “Income Taxes (Topic 740): Improvements to Income Tax Disclosures.” This standard enhances disclosures related to income taxes, including the rate reconciliation and information on income taxes paid. This ASU becomes effective for annual periods beginning after December 15, 2024. The Company is currently assessing the impact of this ASU.

In November 2023, the FASB issued ASU No. 2023-07, “Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures.” This standard requires disclosure of significant segment expenses and other segment items by reportable segment. The Company adopted ASU No. 2023-07 effective December 31, 2024, on a retrospective basis, the impact of which is limited to additional segment expense disclosures in the notes to the Company’s consolidated financial statements.

3. 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:

(In thousands)	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 22,245	\$ —	\$ —	\$ 22,245
Marketable securities	—	179,326	—	179,326
Total assets	<u>\$ 22,245</u>	<u>\$ 179,326</u>	<u>\$ —</u>	<u>\$ 201,571</u>
Liabilities:				
Contingent consideration	\$ —	\$ —	\$ 8,700	\$ 8,700
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 8,700</u>	<u>\$ 8,700</u>

(In thousands)	December 31, 2023			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 32,177	\$ —	\$ —	\$ 32,177
Marketable securities	—	141,999	—	141,999
Total assets	<u>\$ 32,177</u>	<u>\$ 141,999</u>	<u>\$ —</u>	<u>\$ 174,176</u>
Liabilities:				
Contingent consideration	\$ —	\$ —	\$ 6,200	\$ 6,200
Total liabilities	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,200</u>	<u>\$ 6,200</u>

As of December 31, 2024 and 2023, the Company’s cash equivalents consisted of a money market fund, which was valued based upon Level 1 inputs. The Company’s marketable securities as of December 31, 2024 consisted of commercial paper and corporate debt, foreign government agency debt and U.S. government and government agency debt securities, which were valued based upon Level 2 inputs. The Company’s marketable securities as of December 31, 2023 consisted of commercial paper and corporate debt, asset-backed debt, foreign government agency debt and U.S. government and 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. During the years ended December 31, 2024 and 2023, there were no transfers into or out of Level 3.

The overall \$2.5 million increase in the fair value of the contingent consideration liability during the year ended December 31, 2024 was primarily due to changes in estimated sales levels, changes to the probability of success for certain product candidates and the passage of time, offset by changes in market rates.

As of December 31, 2024 and 2023 the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

(In thousands)	December 31, 2024			
	Book Value	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities ⁽¹⁾	\$ 105,154	\$ 192	\$ (156)	\$ 105,190
Commercial paper	4,720	—	(1)	4,719
Foreign government agency debt securities	4,911	16	—	4,927
U.S. government and government agency debt securities ⁽²⁾	64,454	47	(11)	64,490
Total marketable securities	<u>\$ 179,239</u>	<u>\$ 255</u>	<u>\$ (168)</u>	<u>\$ 179,326</u>

⁽¹⁾ Included in Corporate debt securities is \$59.8 million with maturity dates between one and three years.

⁽²⁾ Included in U.S. government and government agency debt securities is \$30.5 million with maturity dates between one and three years.

(In thousands)	December 31, 2023			
	Book Value	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities ⁽¹⁾	\$ 52,362	\$ 65	\$ (142)	\$ 52,285
Commercial paper	12,345	2	(1)	12,346
Asset-backed debt securities ⁽²⁾	10,953	42	(30)	10,965
Foreign government agency debt securities ⁽³⁾	4,698	43	—	4,741
U.S. government and government agency debt securities ⁽⁴⁾	61,750	8	(96)	61,662
Total marketable securities	<u>\$ 142,108</u>	<u>\$ 160</u>	<u>\$ (269)</u>	<u>\$ 141,999</u>

⁽¹⁾ Included in Corporate debt securities is \$28.0 million with maturity dates between one and two years.

⁽²⁾ Included in Asset-backed debt securities is \$6.2 million with maturity dates between one and three years.

⁽³⁾ Included in Foreign government agency debt securities is \$4.7 million with a maturity date between one and two years.

⁽⁴⁾ Included in U.S. government and government agency debt securities is \$23.9 million with maturity dates between one and two years.

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

(In thousands)	December 31, 2024	December 31, 2023
Computer equipment	\$ 1,198	\$ 1,253
Lab equipment	3,137	3,154
Furniture and fixtures	661	558
Leasehold improvements	817	817
Property and equipment, gross	5,813	5,782
Accumulated depreciation	(4,805)	(4,162)
Property and equipment, net	<u>\$ 1,008</u>	<u>\$ 1,620</u>

Depreciation expense was \$0.7 million and \$0.8 million for the years ended December 31, 2024 and 2023, respectively.

5. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	December 31, 2024	December 31, 2023
Employee compensation expenses	\$ 4,979	\$ 3,910
Research and development expenses	2,173	6,661
Deferred transaction consideration	3,927	—
Licensing expenses	8,645	5,478
Restructuring expenses (Note 15)	163	3,112
Other expenses	446	285
Total accrued expenses	<u>\$ 20,333</u>	<u>\$ 19,446</u>

6. Stockholders' Equity

Preferred Stock

As of December 31, 2024 and 2023, the Company's amended and restated certificate of incorporation (as amended, the "Charter") 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, 2024 and 2023.

Common Stock

As of December 31, 2024 and 2023, the Company's Charter authorized the Company to issue 200,000,000 shares of \$0.00001 par value common stock. There were 107,850,124 and 70,894,889 shares of common stock issued and outstanding as of December 31, 2024 and 2023, 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, 2024.

Warrants

The Company issued warrants to Biosion and Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. ("CTTQ") to purchase, in the aggregate, 14,281,985 shares of the Company's common stock (the "Warrants"). The Warrants have an initial exercise price of \$0.00001 per share, subject to adjustment as provided in the Warrants. The Warrants are immediately exercisable, subject to any applicable overseas direct investment filing that may be required for the holders. The Warrants will terminate when exercised in full. The Company classified the Warrants within equity because they are indexed to the Company's own stock. The Company assigned an estimated fair value of \$44.8 million to the Warrants, which was based on the fair value of the Company's common stock on the date of issuance less the nominal exercise price of \$0.00001 per share.

At-The-Market Facility

In April 2023, the Company sold 3.4 million shares of its common stock for aggregate gross proceeds of \$27.5 million, pursuant to a sales agreement with Leerink Partners LLC (formerly SVB Securities LLC) and Cantor Fitzgerald & Co., as sales agents, dated February 23, 2023. The Company paid selling commissions of \$0.8 million in connection with the sale.

Private Placement

In November 2024, the Company closed a private placement in which it sold approximately 35.6 million shares of its common stock for aggregate gross proceeds of \$80.0 million. The Company paid placement agent and other fees of \$5.1 million in connection with the private placement.

7. Stock-Based Awards

2024 Inducement Plan

In November 2024, the Company's board of directors adopted the 2024 Inducement Plan (the "2024 Inducement Plan"). The 2024 Inducement Plan is a non-stockholder approved stock plan adopted pursuant to the "inducement exception" provided under Nasdaq listing rules. The only employees eligible to receive grants of awards under the 2024 Inducement Plan are individuals who satisfy the standards for inducement grants under Nasdaq rules, generally including individuals who were not previously an employee or director of the Company. Under the terms of the 2024 Inducement Plan, the Company may grant up to 2,000,000 shares of common stock pursuant to nonqualified stock options, stock appreciation rights, restricted stock awards, RSUs, and other stock awards. The shares of common stock underlying any awards that expire, or are otherwise terminated, settled in cash or repurchased by the Company under the 2024 Inducement Plan will be added back to the shares of common stock available for issuance under the 2024 Inducement Plan. As of December 31, 2024, 1,194,000 shares remained available for grant under the 2024 Inducement Plan. The Company had 626,000 stock options and 180,000 RSUs outstanding as of December 31, 2024 under the 2024 Inducement Plan.

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 automatically increased on January 1 of each year which ended 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, 2024, 4,820,283 shares remained available for grant under the 2015 Plan. As of January 1, 2025, the number of shares of common stock that may be issued under the 2015 Plan was automatically increased by 4,314,004 shares. The Company had 5,548,563 stock options and 2,096,151 RSUs outstanding as of December 31, 2024 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 329,000 stock options outstanding as of December 31, 2024 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

In August 2012, the Company's board of directors adopted the 2012 Plan and the Company's stockholders approved the 2012 Plan. Upon the 2015 Plan becoming effective, no further grants can be made under the 2012 Plan. The Company had 218,404 stock options outstanding as of December 31, 2024 under the 2012 Plan.

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, 2024 and 2023 were as follows:

	Year Ended December 31,	
	2024	2023
Risk-free interest rate	3.91 %	3.55 %
Expected term (in years)	6.0	6.2
Expected volatility	81.62 %	77.73 %
Expected dividend yield	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, 2024 and 2023:

(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, 2022	5,167,164	\$ 16.04	7.2	\$ 15,288
Granted	2,241,550	15.62		
Exercised	(71,092)	1.31		473
Forfeited and cancelled	(918,167)	16.85		
Outstanding as of December 31, 2023	6,419,455	\$ 15.94	7.1	\$ 14
Granted	2,608,700	1.86		
Exercised	(162,388)	1.31		285
Forfeited and cancelled	(2,143,800)	15.06		
Outstanding as of December 31, 2024	6,721,967	\$ 11.12	6.8	\$ 2,968
Options vested and expected to vest as of December 31, 2024	6,721,967	\$ 11.12	6.8	\$ 2,968
Options exercisable as of December 31, 2024	3,555,450	\$ 15.39	5.0	\$ 944

The weighted average grant date fair value of stock options granted during the years ended December 31, 2024 and 2023 was \$1.34 and \$10.98 per share, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2024 and 2023.

(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, 2022	1,520,730	\$ 14.02	
Granted	993,662	15.17	
Vested	(745,279)	11.72	\$ 8,262
Forfeited and cancelled	(247,173)	15.15	
Outstanding as of December 31, 2023	1,521,940	\$ 15.72	
Granted	2,852,573	1.39	
Vested	(1,473,327)	5.51	\$ 2,959
Forfeited and cancelled	(625,035)	13.03	
Outstanding as of December 31, 2024	<u>2,276,151</u>	\$ 5.12	

Stock-Based Compensation

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

(In thousands)	Year Ended December 31,	
	2024	2023
Cost of revenue	\$ 938	\$ 1,456
Research and development	3,135	6,801
General and administrative	6,783	12,285
Total stock-based compensation expense	<u>\$ 10,856</u>	<u>\$ 20,542</u>

As of December 31, 2024, the Company had unrecognized stock-based compensation expense for stock options and RSUs of \$10.0 million and \$7.6 million, respectively, which is expected to be recognized over weighted average periods of 2.3 years and 1.9 years, respectively.

8. Net Loss per Share

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

(In thousands, except for share and per share data)	Year Ended December 31,	
	2024	2023
Numerator:		
Net loss	\$ (132,065)	\$ (88,481)
Denominator:		
Weighted average shares of common stock outstanding, basic and diluted	<u>77,296,665</u>	<u>69,808,855</u>
Net loss per share, basic and diluted	<u>\$ (1.71)</u>	<u>\$ (1.27)</u>

The Company's potentially dilutive securities, which included stock options and RSUs, have been excluded from the computation of diluted net loss per share since the effect would be to reduce the net loss per share. Therefore, the weighted average number of shares of common stock outstanding used to calculate both basic and diluted net loss per share is the same. For the year ended December 31, 2024, the basic and diluted weighted-average shares outstanding

included the Warrants, as there were no outstanding contingencies associated with the vesting or exercisability of the Warrants.

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, 2024 and 2023. All share amounts presented in the table below represent the total number outstanding as of December 31 of each year.

	December 31,	
	2024	2023
Options to purchase common stock	6,721,967	6,419,455
Restricted stock unit awards	2,276,151	1,521,940
Total potential shares of common stock	<u>8,998,118</u>	<u>7,941,395</u>

9. Leases

The Company has operating leases for office space and laboratory facilities. The components of lease expense were as follows:

(In thousands)	Year Ended December 31,	
	2024	2023
Operating lease expense	\$ 862	\$ 1,092

Rent expense was \$0.9 million and \$1.1 million for the years ended December 31, 2024 and 2023, respectively, which was recognized on a straight-line basis over the term of the lease.

Operating Leases

Agreements for Office and Laboratory Space

The Company had a sublease agreement pursuant to which it subleased 33,019 square feet of office space for its headquarters in Wayne, Pennsylvania, which expired on October 31, 2023.

In May 2023, the Company entered into a new lease agreement pursuant to which it leases 11,564 square feet of office space for its headquarters in Wayne, Pennsylvania. The lease commenced on November 1, 2023 and has a term that runs through February 2029.

In February 2019, the Company entered into a sublease agreement 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 May 2029. In January 2023, the Company amended the sublease agreement to add an additional 6,261 square feet of office and laboratory space effective February 2023. The Company exercised its option to terminate the leasing of the additional space effective as of June 30, 2024.

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

(In thousands)	December 31, 2024	December 31, 2023
Operating Leases:		
Gross cost	\$ 4,530	\$ 5,094
Accumulated amortization	(1,688)	(1,235)
Other assets	<u>\$ 2,842</u>	<u>\$ 3,859</u>
Current portion of lease liabilities	\$ 481	\$ 426
Other liabilities	2,117	3,074
Total operating lease liabilities	<u>\$ 2,598</u>	<u>\$ 3,500</u>

Amortization expense related to operating lease right-of-use assets and accretion of operating lease liabilities totaled \$0.5 million and \$0.8 million for the years ended December 31, 2024 and 2023, respectively.

Supplemental information related to operating leases is as follows:

(In thousands, except for years and percentages)	Year Ended December 31,	
	2024	2023
Supplemental Cash Flow Lease Information:		
Operating cash flows from operating leases	\$ 736	\$ 974
Leased assets obtained in exchange for new operating lease liabilities	\$ —	\$ 2,010
Weighted-Average Remaining Lease Term (in years):		
Operating leases	4.3	5.3
Weighted-Average Discount Rate:		
Operating leases	10.1 %	10.2 %

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

(In thousands)	Operating Leases
Year Ending December 31,	
2025	694
2026	742
2027	760
2028	779
2029	260
Total undiscounted lease payments	3,235
Less: unrecognized interest	(637)
Total lease liability	<u>\$ 2,598</u>

10. Income Taxes

During the years ended December 31, 2024 and 2023, the Company did not record an income tax benefit for net operating losses incurred in each year due to the uncertainty of realizing a benefit from those items.

Loss before income taxes is allocated as follows:

(In thousands)	Year Ended December 31,	
	2024	2023
U.S. operations	\$ (132,065)	\$ (88,848)
Foreign operations	—	—
Loss before income taxes	<u>\$ (132,065)</u>	<u>\$ (88,848)</u>

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,	
	2024	2023
Federal statutory income tax rate	(21.0)%	(21.0)%
State taxes, net of federal benefit	(2.1)	(1.7)
Impact of state rate changes	(1.1)	17.7
Research and development tax credits	(1.1)	(5.9)
Excess equity compensation tax benefit, net of officer limitation	0.8	0.6
Revaluation of contingent consideration	0.4	(6.3)
Non-deductible royalty payments	1.8	4.3
Change in deferred tax asset valuation allowance	22.1	11.7
Other	0.2	0.2
Effective income tax rate	(0.0)%	(0.4)%

Deferred tax liabilities, net consisted of the following:

(In thousands)	December 31,	
	2024	2023
Deferred tax assets:		
Net operating loss carryforwards	\$ 120,361	\$ 119,155
Capitalized start-up costs	3,469	3,812
Research and development tax credit carryforwards	21,954	20,505
Section 174 research and development capitalization	31,185	30,984
Capitalized research and development expense	2,145	2,359
Stock-based compensation expense	19,101	18,055
Accrued compensation	791	1,219
Lease liabilities	588	774
Deferred income	5,510	—
IPR&D	20,004	—
Other	408	407
Total deferred tax assets	225,516	197,270
Deferred tax liabilities:		
Property and equipment	(56)	(187)
Right-to-use assets	(642)	(853)
Other	(458)	(1,106)
Total deferred tax liabilities	(1,156)	(2,146)
Valuation allowance	(224,360)	(195,124)
Deferred tax liabilities, net	\$ —	\$ —

As of December 31, 2024, the Company had federal and state net operating loss ("NOL") carryforwards of \$469.4 million and \$401.1 million, respectively, which will begin to expire in 2032. As of December 31, 2024, the Company also had federal research and development tax credit carryforwards of \$21.9 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 2030. 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, 2024. Although the Company has experienced Section 382 ownership changes since 2012, the Company 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, 2024. 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, 2024 and 2023. 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, 2024 and 2023, which related primarily to the increases in NOLs, capitalized research and development costs, and research and development tax credit carryforwards, were as follows:

(In thousands)	Year Ended December 31,	
	2024	2023
Valuation allowance at beginning of year	\$ (195,124)	\$ (184,688)
Decreases recorded as benefit to income tax provision	—	—
Increases recorded to income tax provision	(29,236)	(10,436)
Valuation allowance as of end of year	<u>\$ (224,360)</u>	<u>\$ (195,124)</u>

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 2021 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. The Company has not recorded any amounts for unrecognized tax benefits as of December 31, 2024 and 2023.

11. Related Party Transaction

Anand Mehra, a member of the Company's board of directors, purchased 666,666 shares of the Company's common stock at a price per share of \$2.25 in connection with a private placement in November 2024.

12. Agreements Related to Intellectual Property

Exclusive License Agreement – Biosion, Inc.

In November 2024, the Company entered into an exclusive license agreement (the "Biosion Agreement") with Biosion, pursuant to which it received the exclusive rights to develop, manufacture and commercialize bosakitug (ATI-045) and ATI-052 worldwide, excluding Mainland China, Macau, Hong Kong and Taiwan ("Greater China"). In connection with the Biosion Agreement, the Company also entered into a collaboration agreement (the "CTTQ Agreement") with Biosion and CTTQ, a licensee of bosakitug in Greater China.

In partial consideration of the rights and licenses under the Biosion Agreement and CTTQ Agreement, the Company, agreed to, in the aggregate, (i) pay \$30.0 million in upfront cash consideration, plus \$4.5 million for the reimbursement of certain development costs, (ii) issue the Warrants, and (iii) pay \$6.2 million for the reimbursement of certain development costs and drug product material as set forth in the Biosion Agreement. The Company determined that the transaction was an acquisition of assets with no alternative future use and therefore expensed as incurred the fair value of the consideration given of \$85.6 million as a component of in-process research and development expense during the year ended December 31, 2024. The Company incurred \$1.3 million in expenses related to this transaction which were expensed as incurred.

In addition, the Company agreed to pay, in the aggregate, (i) up to \$125 million upon the achievement of specified regulatory milestones commencing with product approval, (ii) up to \$795 million upon the achievement of specified sales milestones, (iii) a tiered low-to-mid single digit royalty based upon a percentage of annual net sales, subject to specified reductions as set forth in the Biosion Agreement, and (iv) a portion of any sublicense consideration received from the grant of any sublicense or similar rights under any of the rights or licenses granted to the Company under the Biosion Agreement. The Company will expense these payments in the period when either they are determined to be probable of occurring or when the payment is triggered.

The Warrants have an initial exercise price of \$0.00001 per share, subject to adjustment as provided in the Warrants. The Warrants are immediately exercisable, subject to any applicable overseas direct investment filing that may be required for the holders. The Warrants will terminate when exercised in full. The Company classified the Warrants within equity because they are indexed to the Company's own stock. The Company assigned an estimated fair value of \$44.8 million to the Warrants, which was based on the fair value of the Company's common stock on the date of issuance less the nominal exercise price of \$0.00001 per share.

License Agreement – Sun Pharmaceutical Industries, Inc.

In December 2023, the Company entered into an exclusive patent license agreement with Sun Pharmaceutical Industries, Inc. ("Sun Pharma"). Under the license agreement, the Company granted Sun Pharma exclusive rights under certain patents that the Company exclusively licenses from a third party. The patents relate to the use of deuruxolitinib, Sun Pharma's Janus kinase ("JAK") inhibitor, or other isotopic forms of ruxolitinib, to treat alopecia areata or androgenetic alopecia. Under the license agreement, Sun Pharma has paid the Company upfront and regulatory payments, and has agreed to pay the Company other regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a mid single-digit tiered royalty calculated as a percentage of Sun Pharma's net sales. The Company has separate contractual obligations under which the Company has agreed to pay to third parties a portion of the consideration it may receive under the license agreement.

The Company recognized \$3.0 million and \$15.0 million of licensing revenue during the years ended December 31, 2024 and 2023, respectively.

License Agreement – Pediatrix Therapeutics, Inc.

In November 2022, the Company entered into a license agreement with Pediatrix Therapeutics, Inc. ("Pediatrix"), under which the Company granted Pediatrix the exclusive rights to develop, manufacture and commercialize lepzacitinib in Greater China. Pediatrix has paid the Company an upfront payment, and has agreed to pay the Company development, regulatory and commercial milestone payments upon the achievement of specified milestones set forth in the agreement, and a tiered royalty ranging from a low-to-high single digit percentage of net sales of lepzacitinib by Pediatrix in Greater China. A portion of consideration received from Pediatrix is payable to the former Confluence equity holders as described below under "—Agreement and Plan of Merger - Confluence."

License Agreement – Eli Lilly and Company

In August 2022, the Company entered into a non-exclusive patent license agreement with Eli Lilly and Company ("Lilly"). Under the license agreement, the Company granted Lilly non-exclusive rights under certain patents and patent applications that the Company exclusively licenses from a third party. The patents and patent applications relate to the use of baricitinib, Lilly's JAK inhibitor, to treat alopecia areata. Under the license agreement, Lilly has paid the Company upfront, regulatory and certain commercial milestone payments, and agreed to pay the Company anniversary payments and other commercial milestone payments upon the achievement of specified milestones as set forth in the agreement, and a low single-digit royalty calculated as a percentage of Lilly's net sales of baricitinib for the treatment of alopecia areata. The Company has separate contractual obligations under which the Company has agreed to pay to third parties an amount equal to any regulatory and commercial milestone payments it receives under the Lilly license agreement, as well as a portion of the upfront consideration and a portion of the royalties it may receive under the license agreement. In July 2024, the Company entered into a royalty purchase agreement with OCM IP Healthcare Portfolio LP, an investment vehicle for Ontario Municipal Employees Retirement System ("OMERS"), pursuant to which the Company sold to OMERS a portion of the Company's future royalty payments and the remaining anniversary milestones associated with the license to Lilly (see Note 13).

During the years ended December 31, 2024 and 2023, the Company recognized licensing revenue under this agreement of \$13.2 million and \$12.7 million, respectively, from Lilly, a portion of which was payable to third parties. As of December 31, 2024, we recorded a receivable of \$8.6 million in other current assets, which represents licensing revenue due to third parties.

Asset Purchase Agreement – EPI Health, LLC

In October 2019, the Company sold RHOFADÉ (oxymetazoline hydrochloride) cream, 1% (“RHOFADÉ”) to EPI Health, LLC (“EPI Health”) pursuant to an asset purchase agreement. In July 2023, EPI Health filed a voluntary petition for relief under Chapter 11 of the United States Bankruptcy Code. Through the bankruptcy process, EPI Health and its parent company, Novan, Inc., sold the RHOFADÉ assets to a third party, which excluded the Company’s asset purchase agreement with EPI Health and the outstanding amounts due. The sale was approved by the bankruptcy court in September 2023. As a result of the bankruptcy proceedings, all amounts that were due and outstanding by EPI Health have been fully reserved.

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, 2024 and December 31, 2023, the balance of the Company’s contingent consideration liability was \$8.7 million and \$6.2 million, respectively (see Note 3).

13. Sale of Future Royalties

In July 2024, the Company entered into a royalty purchase agreement with OMERS. Under the royalty purchase agreement, the Company sold to OMERS a portion of the Company’s future royalty payments and the remaining anniversary milestones associated with the Company’s existing license to Lilly relating to OLUMIANT® (baricitinib) for the treatment of alopecia areata.

Under the terms of the royalty purchase agreement, the Company received an upfront payment of \$26.5 million. In exchange, OMERS acquired a portion of the royalty payable by Lilly to the Company for worldwide net sales of OLUMIANT for the treatment of alopecia areata from April 1, 2024 through the remainder of the royalty term under the Company’s license agreement with Lilly, and 100% of the remaining anniversary milestone payments payable by Lilly to the Company under the license agreement.

The Company evaluated the arrangement and concluded that the proceeds from the sale of future royalties should be recorded as deferred income on the consolidated balance sheet, as the criteria for debt classification were not met in accordance with ASC Topic 470. In particular, the Company does not have significant continuing involvement in the generation of the cash flows due to OMERS and there are no guaranteed rates of return to OMERS. The Company recognizes non-cash royalty income under the “units-of-revenue” method in the consolidated statements of operations and comprehensive loss. The Company initially recorded \$0.7 million as a receivable for royalties earned in the second quarter of 2024 and recorded \$25.8 million as deferred income related to the sale of future royalties. For the year ended December 31, 2024, the Company recognized \$1.9 million of non-cash royalty income. As of December 31, 2024, the current and non-current portions of the remaining deferred income recognized under the units-of revenue method were \$3.9 million and \$20.0 million, respectively.

14. 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 \$0.4 million and \$0.7 million for the years ended December 31, 2024 and 2023, respectively.

15. Restructuring Charges

In December 2023, the Company's board of directors approved a reduction of the Company's workforce by approximately 46%, which was completed as of December 31, 2024. This action was taken in order to streamline operations, reduce costs and preserve capital. The Company expensed the cost of cash severance payments, other benefits and annual bonus payments for certain terminated employees with retention periods more than the sixty-day minimum retention period over their respective service terms. During the year ended December 31, 2024, the Company recognized severance expense of \$2.7 million and made cash severance payments of \$5.6 million to impacted employees. Of the \$2.7 million of expenses incurred during the year ended December 31, 2024, \$1.5 million, \$1.0 million and \$0.2 million were recorded in research and development expense, general and administrative expense and cost of revenue, respectively, in the consolidated statement of operations and comprehensive loss. During the year ended December 31, 2023, the Company recorded a restructuring charge of \$3.1 million which represents a one-time termination benefit for impacted employees with retention periods less than the minimum retention period, which was triggered immediately upon either terminating or giving notice to the impacted employees. Of the \$3.1 million of expenses incurred during the year ended December 31, 2023, \$2.2 million, \$0.9 million and \$19 thousand were recorded in research and development expense, general and administrative expense and cost of revenue, respectively, in the consolidated statement of operations and comprehensive loss.

16. 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 and earns revenue through licensing of the Company's intellectual property. The contract research segment earns revenue from the provision of laboratory services.

All intersegment revenue has been eliminated in the Company's consolidated statement of operations. All customers and revenue pertaining to the Company's segments are based in the United States and all assets are held in the United States. The Company does not report asset information by segment because it is not regularly provided to the Company's chief executive officer, who is the Company's CODM.

Since inception, the Company has incurred net losses and has an accumulated deficit of \$902.9 million as of December 31, 2024. As such, the CODM uses segment loss from operations for each segment in assessing segment performance by comparing the results of each segment to forecast. All intercompany activity is eliminated in the intersegment elimination column in the tables below.

A reconciliation of operating loss to total consolidated loss before income taxes, for the years ended December 31, 2024 and 2023 is as follows:

(In thousands)				
Year Ended December 31, 2024				
	Therapeutics	Contract Research	Intersegment Elimination	Total
Revenue from external customers	\$ 16,179	\$ 2,541	\$ —	\$ 18,720
Intercompany revenue	—	13,416	(13,416)	—
Cost of revenue	—	15,349	(12,557)	2,792
Bosakitug	299	—	—	299
ATI-2138	4,209	—	—	4,209
ATI-052	1,895	—	—	1,895
Lepzacinib	1,300	—	—	1,300
Zunsemetinib	4,496	—	—	4,496
Discovery	5,775	—	—	5,775
Total Research and development project spend	17,974	—	—	17,974
Personnel	11,446	—	—	11,446
Other research and development expense ⁽¹⁾	5,025	—	—	5,025
Total research and development	34,445	—	(859)	33,586
General and administrative	—	4,035	—	4,035
Licensing	12,666	—	—	12,666
Revaluation of contingent consideration	2,500	—	—	2,500
In-process research and development	86,905	—	—	86,905
Segment operating loss	\$ (120,337)	\$ (3,427)	\$ —	\$ (123,764)
Non-segment general and administrative				18,168
Other income				9,867
Loss before income taxes				(132,065)

(In thousands)				
Year Ended December 31, 2023				
	Therapeutics	Contract Research	Intersegment Elimination	Total
Revenue from external customers	\$ 28,214	\$ 3,035	\$ —	\$ 31,249
Intercompany revenue	—	16,543	(16,543)	—
Cost of revenue	—	18,960	(15,537)	3,423
Bosakitug	—	—	—	—
ATI-2138	12,143	—	—	12,143
ATI-052	—	—	—	—
Lepzacinib	12,129	—	—	12,129
Zunsemetinib	36,461	—	—	36,461
Discovery	6,881	—	—	6,881
Total Research and development project spend	67,614	—	—	67,614
Personnel	18,977	—	—	18,977
Other research and development expense ⁽¹⁾	12,799	—	—	12,799
Total research and development	99,390	—	(1,006)	98,384
General and administrative	—	4,561	—	4,561
Licensing	14,658	—	—	14,658
Revaluation of contingent consideration	(26,900)	—	—	(26,900)
In-process research and development	6,629	—	—	6,629
Segment operating loss	\$ (65,563)	\$ (3,943)	\$ —	\$ (69,506)
Non-segment general and administrative				27,851
Other income				8,509
Loss before income taxes				(88,848)

⁽¹⁾ Other segment items for the Therapeutics segment consist primarily of the following research and development expenses; stock-based compensation, depreciation and amortization, regulatory.

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 principal executive officer and our principal financial officer, we conducted an evaluation of the effectiveness of our disclosure controls and procedures as of December 31, 2024, 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 (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the rules and forms promulgated by the SEC. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the company’s management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our principal executive officer and principal 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, 2024 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.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting as required by Section 404(b) of the Sarbanes-Oxley Act of 2002. Because we are a non-accelerated filer under the SEC rules, management’s report was not subject to attestation by our independent registered public accounting firm.

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, 2024 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

Entry into At-the-Market Facility

On February 27, 2025, we entered into an Amended and Restated Sales Agreement (the “Amended ATM Agreement”) with Leerink Partners LLC (“Leerink”) and Cantor Fitzgerald & Co. (“Cantor”) under which we may offer and sell, from time to time at our sole discretion, shares of our common stock having an aggregate offering price of up to \$100.0 million through Leerink and Cantor as sales agents. The issuance and sale, if any, of common stock under the Amended ATM Agreement will be made pursuant to a registration statement on Form S-3. The Amended ATM Agreement amends and restates the sales agreement with Leerink and Cantor, dated February 23, 2023, which provided for the offer and sale of up to \$200.0 million of our common stock from time to time through Leerink and Cantor as sales agents.

Leerink and Cantor may sell shares of our common stock by any method permitted by law deemed to be an “at the market offering” as defined in Rule 415 of the Securities Act. Leerink and Cantor have agreed to use commercially reasonable efforts to sell our common stock from time to time, based on our instructions (including any price, time or size limits or other customary parameters or conditions we may impose). We will pay Leerink and Cantor a commission equal to three percent (3.0%) of the gross sales proceeds of any common stock sold through Leerink and Cantor under the Amended ATM Agreement. We provided customary representations, warranties and covenants, and the parties have agreed to customary indemnification rights.

We are not obligated to make any sales of common stock under the Amended ATM Agreement. The offering of shares of our common stock pursuant to the Amended ATM Agreement will terminate upon the earlier of (i) the sale of the maximum dollar value of common stock permitted to be sold pursuant to the Amended ATM Agreement or (ii) termination of the Amended ATM Agreement in accordance with its terms.

The foregoing description of the Amended ATM Agreement is not complete and is qualified in its entirety by reference to the full text of the Amended ATM Agreement, a copy of which is filed as an exhibit to this Annual Report.

Entry into Employment Agreement with Neal Walker

On February 26, 2025, our board of directors (the “Board”) appointed Neal Walker as our Chief Executive Officer effective immediately. In connection with such appointment, we have entered into an employment agreement with Dr. Walker, dated February 26, 2025 (the “Walker Employment Agreement”). The Walker Employment Agreement has an initial term of two years and thereafter shall be automatically renewed for successive one-year periods unless either party elects not to renew the agreement at least 90 days prior to the expiration of the applicable term. Dr. Walker will receive an annual base salary of \$615,000, which may be increased by the Board in its sole discretion. Dr. Walker will be eligible to receive a target annual bonus equal to up to 60% of the annual base salary, subject to the achievement of performance goals to be determined by the Board.

Under the Walker Employment Agreement, if Dr. Walker’s employment with the Company ends due to his death or “disability”, his resignation for “good reason” or his termination by the Company other than for “cause,” each as defined in the Walker Employment Agreement, in either case that does not occur on or within three months prior to or 12 months after the effective date of a “change of control” (as defined in the Walker Employment Agreement), he will be entitled to receive (i) continuation of his then-current base salary for a period of 12 months; (ii) any bonuses for the preceding year for which he remains employed through the last day of such year; and (iii) continued health benefits under COBRA for up to 12 months. Dr. Walker would also receive the foregoing benefits in the event his employment is terminated upon non-renewal of the Walker Employment Agreement by the Company.

In the case Dr. Walker’s employment with the Company ends due to his death or “disability,” his resignation for “good reason” or his termination by the Company other than for “cause,” in either case that occurs on or within three months prior to or 12 months after the effective date of a “change of control”, then he will be entitled to receive, in addition to the benefits described in the preceding paragraph, (i) continuation of his then-current base salary for an additional six months; (ii) an additional lump sum payment equal to 150% of his target bonus; (iii) continued health benefits under COBRA for up to an additional six months; and (iv) acceleration of all unvested equity awards.

The foregoing benefits are conditioned, among other things, on Dr. Walker’s compliance with his post-

termination obligations under the Walker Employment Agreement and his execution of a general release of claims in favor of the Company.

Dr. Walker has previously entered into our standard form of indemnification agreement.

The foregoing summary of the Walker Employment Agreement is not complete and is qualified in its entirety by reference to the full text of the Walker Employment Agreement, a copy of which is filed as an exhibit to this Annual Report.

Adoption, Modification and Termination of Rule 10b5-1 Plans and Certain Other Trading Arrangements

On December 12, 2024, Joseph Monahan, our Chief Scientific Officer, adopted a Rule 10b5-1 trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act. Sales may commence under the plan on March 13, 2025 and the plan terminates on December 31, 2025, subject to earlier termination in accordance with its terms. The aggregate number of securities to be sold under the plan is 60,000 shares of common stock.

No other officers or directors (as defined in Rule 16a-1(f) under the Exchange Act) adopted, modified or terminated a “Rule 10b5-1 trading arrangement” or a “non-Rule 10b5-1 trading arrangement” (as each term is defined in Item 408 of Regulation S-K), during the quarter ended December 31, 2024.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The following table sets forth information concerning our directors and executive officers, including their ages as of February 10, 2025. There are no family relationships among any of our directors or executive officers.

For our directors, the biographies below include information, as of February 10, 2025, regarding the specific and particular experience, qualifications, attributes or skills that led to the conclusion that the person should serve as a director of our company.

<i>Name</i>	<i>Age</i>	<i>Position</i>
Executive Officers:		
Neal Walker	55	Chief Executive Officer, Chair of the Board of Directors
Hugh Davis, Ph.D.	66	President, Chief Operating Officer and Director
Kevin Balthaser	38	Chief Financial Officer
Joseph Monahan, Ph.D.	69	Chief Scientific Officer
James Loerop	61	Chief Business Officer
Non-management Directors:		
Christopher Molineaux	59	Lead Independent Director
Maxine Gowen, Ph.D.	66	Director
William Humphries	58	Director
Anand Mehra, M.D.	49	Director
Vincent Milano	61	Director
Andrew Schiff, M.D.	59	Director

Executive Officers

Neal Walker

Neal Walker co-founded our company and has served as our Chief Executive Officer since February 2025. He previously served as our Interim Chief Executive Officer from January 2024 to February 2025, as our President from January 2024 to November 2024, and as our Chief Executive Officer and President from our inception in 2012 until December 2022. Dr. Walker has also served as a member of our Board since our inception and currently serves as its Chair. Dr. Walker's term of office as a director will expire at the 2025 Annual Meeting of Stockholders. Dr. Walker co-founded NeXeption, LLC, a biopharmaceutical assets management company, in 2012. Dr. Walker co-founded and served as President and Chief Executive Officer and a member of the board of directors of Vicept Therapeutics, Inc., a dermatology-focused specialty pharmaceutical company, from 2009 until its acquisition by Allergan, Inc. in 2011. Previously, Dr. Walker co-founded and led a number of life science companies, including Octagon Research Solutions, Inc., a software and services provider to biopharmaceutical companies (acquired by Accenture plc), Trigenesis Therapeutics, Inc., a specialty dermatology company, where he served as Chief Medical Officer (acquired by Dr. Reddy's Laboratories Inc.), and Cutix Inc., a commercial dermatology company. He began his pharmaceutical industry career at Johnson and Johnson, Inc. Dr. Walker is a director of Aldeyra Therapeutics, Inc., a publicly held biotechnology company, as well as several private companies. Dr. Walker received an M.B.A. degree from The Wharton School of the University of Pennsylvania, a Doctor of Osteopathic Medicine degree from the Philadelphia College of Osteopathic Medicine and a B.A. degree in Biology from Lehigh University. Dr. Walker's experience as a board-certified dermatologist and the founder of our company and other pharmaceutical companies, his background in clinical and drug development in dermatology and other fields, and his knowledge of the pharmaceutical industry contributed to the conclusion of our Board that he should serve as a director of our company.

Hugh Davis

Hugh Davis has served as our President and Chief Operating Officer, and as a member of our Board, since November 2024. Dr. Davis's term of office as a director will expire at the 2027 Annual Meeting of Stockholders. He previously held various roles at Biosion, Inc., a biopharmaceutical company, beginning in March 2020, including as Chief Operating Officer of Biosion Inc., President of Biosion USA, Inc., and, most recently, as Biosion's Chief Business & Development Officer and President. Dr. Davis has also served as a member of the board of directors of Biosion, Inc. since

March 2020. From 2018 to February 2020, Dr. Davis served as Chief Business Officer at Frontage Laboratories, Inc. He previously served in a series of leadership roles at Janssen R&D/Johnson & Johnson, including as Vice President & Head, Biologics Development Sciences, Biophysics and Laboratory Operations. Dr. Davis's previous biopharmaceutical experience includes leadership roles at GlaxoSmithKline and Rhone-Poulenc Rorer. Dr. Davis earned Ph.D. and M.S. degrees in Biochemistry from Villanova University and a B.S. degree in Chemistry from Gannon University. Our Board believes that Dr. Davis' extensive scientific leadership experience with pharmaceutical and biotechnology companies qualifies him to serve as a director of our company.

Kevin Balthaser

Kevin Balthaser has served as our Chief Financial Officer since January 2023. Mr. Balthaser has served in roles of increasing responsibility at our company since 2017, most recently as Vice President, Finance from January 2022 until his appointment as Chief Financial Officer. Before joining our company, he held positions of increasing responsibility within the accounting and finance department at Lannett Company, Inc., a publicly traded generic pharmaceutical company, where he was also a member of the team responsible for executing capital market transactions and acquisitions. Mr. Balthaser began his career with the accounting firm PricewaterhouseCoopers LLP. Mr. Balthaser is a certified public accountant in Pennsylvania. He received his B.S. degree in finance from Pennsylvania State University and his M.B.A. degree from Villanova University.

Joseph Monahan, Ph.D.

Joseph Monahan, Ph.D., has served as our Chief Scientific Officer since January 2021. From 2017 to January 2021, Dr. Monahan served as our Executive Vice President, Research and Development. In 2010, Dr. Monahan founded a biotechnology company, Confluence Life Sciences, Inc., and functioned as its Chief Scientific Officer until our acquisition of Confluence in 2017. He has also held multiple research leadership positions at Pfizer Inc., including Executive Director, Inflammation Research, global kinase platform leadership team lead; site head of enzymology and biophysics, and inflammation research and development lead. He has held adjunct and visiting professor positions at Washington University Medical School, University of Missouri and University of California, Los Angeles School of Medicine. Dr. Monahan received his B.S. degree in biochemistry from the University of New York at Buffalo and a Ph.D. degree in biochemistry from the University of South Carolina.

James Loerop

James Loerop has served as our Chief Business Officer since January 2022. From July 2019 to January 2022, Mr. Loerop served as Executive Vice President, Business Development and Strategic Planning at Anika Therapeutics, Inc., a publicly held company focused on products for joint preservation, where he was responsible for global business development activities. From 2017 to July 2019, Mr. Loerop served as Chief Corporate Development Officer for Lupin Pharmaceuticals, Inc., where he was a member of the company's Executive Leadership Team and was responsible for global business development and corporate development activities. Prior to joining Lupin, Mr. Loerop held senior leadership roles at various companies in the pharmaceutical and life sciences industry, including at Alexion Pharmaceuticals, Inc. as Senior Vice President of Global Business Development, GlaxoSmithKline as Vice President of North America Business Development, and Stiefel Laboratories, Inc. as Senior Vice President of Global Corporate Development, prior to GSK's acquisition of Stiefel. Mr. Loerop received a B.S. degree in marketing from Western Michigan University.

Non-Management Directors

Christopher Molineaux

Christopher Molineaux has served as Lead Independent Director of our Board since January 2023, having previously served as Chair since June 2019. He has served as a member of our Board since 2014. Mr. Molineaux's term of office as a director will expire at the 2027 Annual Meeting of Stockholders. Since 2010, Mr. Molineaux has served as President and Chief Executive Officer of Life Sciences Pennsylvania, formerly Pennsylvania Bio, a pharmaceutical and biotech industry advocacy organization, and previously served as its Senior Vice President, Membership Services. Mr. Molineaux previously served as worldwide Vice President of Pharmaceutical Communications and Public Affairs for Johnson & Johnson, a global healthcare company. Mr. Molineaux also served as Vice President for Public Affairs at the Pharmaceutical Research and Manufacturers of America (PhRMA). He received a B.A. degree from the College of the

Holy Cross. Our Board believes that Mr. Molineaux's substantial pharmaceutical and biotechnology industry experience qualifies him to serve as a director of our company.

Maxine Gowen, Ph.D.

Maxine Gowen has served as a member of our Board since July 2019. Dr. Gowen's term of office as a director will expire at the 2026 Annual Meeting of Stockholders. Dr. Gowen previously served as the part-time Chief Executive Officer of TamuroBio Inc., a biotechnology company, from August 2019 to December 2021. Dr. Gowen founded Trevena, Inc., a publicly held biopharmaceutical company, and served as its President and Chief Executive Officer from 2007 until 2018. Prior to this, Dr. Gowen held a variety of leadership roles at GlaxoSmithKline (GSK) over a period of fifteen years. Dr. Gowen was previously President and Managing Partner at SR One, the venture capital subsidiary of GSK, where she led its investments in, and served on the board of directors of, numerous companies. Until 2002, Dr. Gowen was Vice President, Drug Discovery, Musculoskeletal Diseases at GSK, responsible for drug discovery and early development for osteoporosis, arthritis and metastatic bone disease. Dr. Gowen held a tenured academic position in the School of Pharmacology, University of Bath, UK from 1989 to 1992. Dr. Gowen currently serves on the boards of directors of the publicly held companies Merus N.V. and as chair of Passage Bio, Inc. Within the past five years, Dr. Gowen served as a director of the publicly held companies Trevena, Inc., Aceragen, Inc. (formerly known as Idera Pharmaceuticals, Inc.) and Akebia Therapeutics, Inc. Dr. Gowen received a B.Sc. in biochemistry from the University of Bristol, UK, then received a Ph.D. in cell biology from the University of Sheffield, UK, and received an M.B.A from The Wharton School of the University of Pennsylvania. Dr. Gowen also received a D.Sc. from the University of Bath, UK. Our Board believes that Dr. Gowen's extensive leadership experience with pharmaceutical and biotechnology companies qualifies her to serve as a director of our company.

William Humphries

William Humphries has served as a member of our Board since 2016. Mr. Humphries's term of office as a director will expire at the 2025 Annual Meeting of Stockholders. Mr. Humphries has served as the Chief Executive Officer of MedPharm, a contract development and manufacturing organization, since January 2025. From June 2023 to January 2025, he served as the Chief Executive Officer and member of the board of directors of Alcam Corporation, a contract development and manufacturing organization. From May 2021 to May 2023, Mr. Humphries served as the Chief Executive Officer of Isosceles Pharmaceuticals Inc, a biotechnology company. From 2018 to December 2020, Mr. Humphries served as President of Ortho Dermatologics, the dermatology division of Bausch Health Companies, Inc., and previously served as its Executive Vice President, Company Group Chairman for Dermatology and OraPharma from 2017 to 2018. From 2012 to 2016, he served as President and Chief Executive Officer of the North American business of Merz, Inc., an affiliate of Merz Pharma Group, a specialty healthcare company. From 2006 to 2012, Mr. Humphries served in a number of leadership positions with Stiefel Laboratories, Inc., a dermatology pharmaceutical company, including as its Chief Commercial Officer and then as President beginning in 2008. Stiefel was acquired by GSK in 2009, after which Mr. Humphries served as the President of Dermatology for Stiefel from 2009 until 2012. Mr. Humphries previously held multiple senior executive roles in sales and marketing, business development and international marketing for Allergan, Inc., concluding as Vice President of its U.S. skincare business. Mr. Humphries currently serves as a director of the publicly held company Clearside Biomedical, Inc. Within the past five years, he served as a member of the boards of directors of the publicly held companies PhaseBio Pharmaceuticals, Inc. and STRATA Skin Sciences, Inc, as well as Bryn Pharmaceuticals and SKNV. He received a B.A. degree from Bucknell University and an M.B.A. degree from Pepperdine University. Our Board believes that Mr. Humphries' experience as a pharmaceutical company executive provides him with the qualifications and skills to serve as a director of our company.

Anand Mehra, M.D.

Anand Mehra, M.D. has served as a member of our Board since 2014. Dr. Mehra's term of office as a director will expire at the 2026 Annual Meeting of Stockholders. Dr. Mehra has served as a founding partner of Forge Life Science Partners, a biotech investment firm, since its inception in May 2023. Dr. Mehra joined Sofinnova Investments, Inc. (fka Sofinnova Ventures, Inc.), a biotech investment firm, in 2007 and served as a managing general partner until January 2020. Prior to joining Sofinnova, Dr. Mehra worked in J.P. Morgan's private equity and venture capital group, and before that, Dr. Mehra was a consultant in McKinsey & Company's pharmaceutical practice. Dr. Mehra currently serves as the chair of the board of directors of the publicly held company Merus N.V. Dr. Mehra received a B.A. degree in political philosophy from the University of Virginia and an M.D. degree from Columbia University's College of Physicians and Surgeons. Our

Board believes that Dr. Mehra's extensive experience in the life sciences industry, his service on the boards of directors of other public life sciences companies and his extensive leadership experience qualify him to serve as a director of our company.

Vincent Milano

Vincent Milano has served as a member of our Board since January 2020. Dr. Milano's term of office as a director will expire at the 2027 Annual Meeting of Stockholders. Mr. Milano most recently served as Chair of the board of directors of Aceragen, Inc. (formerly known as Idera Pharmaceuticals, Inc.), a publicly held biopharmaceutical company, from 2022 to August 2023, having previously served as Idera's President and Chief Executive Officer and a member of Idera's board of directors since 2014. From 1996 to 2014, Mr. Milano served in increasingly senior roles at ViroPharma Inc., a pharmaceutical company acquired by Shire plc in 2014, most recently as Chairman, President and Chief Executive Officer from 2008 to 2014. From 1985 to 1996, Mr. Milano served in increasingly senior roles, most recently as a senior manager, at KPMG LLP, an independent registered public accounting firm. Mr. Milano currently serves on the boards of directors of BioCryst Pharmaceuticals, Inc., a publicly held company, and Life Sciences Cares Philadelphia, a non-profit organization. Within the past five years, Mr. Milano served on the board of directors of Venatorx Pharmaceuticals, Inc., a privately held company. Mr. Milano received a B.S. degree in Accounting from Rider College. Our Board believes that Mr. Milano's extensive leadership experience with pharmaceutical and biotechnology companies qualifies him to serve as a director of our company.

Andrew Schiff, M.D.

Andrew Schiff has served as a member of our Board since 2017. Dr. Schiff's term of office as a director will expire at the 2025 Annual Meeting of Stockholders. Dr. Schiff joined Aisling Capital, an investment firm, in 1999 and currently serves as one of its managing partners. Prior to joining Aisling Capital, Dr. Schiff practiced internal medicine for six years at The New York Presbyterian Hospital, where he maintains his position as a Clinical Assistant Professor of Medicine. Dr. Schiff currently serves on the board of directors of the publicly held company Monte Rosa Therapeutics, Inc. Dr. Schiff also currently serves on the board of directors of the privately held company Dren Bio. He is a board member of the Visiting Nurse Service of New York, as well as other charitable organizations. Dr. Schiff received an M.D. degree from Cornell University Medical College, an M.B.A. degree from Columbia University, and a B.S. degree with honors in Neuroscience from Brown University. Our Board believes that Dr. Schiff's medical background and venture capital experience qualify him to serve as a director of our company.

Corporate Governance

Code of Ethics

We have adopted the Aclaris Therapeutics, Inc. Code of Business Conduct and Ethics that applies to all officers, directors and employees. The Code of Business Conduct and Ethics is available on our website at www.aclaristx.com. If we make any substantive amendments to the Code of Business Conduct and Ethics or grant any waiver from a provision of the Code of Business Conduct and Ethics to any executive officer or director, we will promptly disclose the nature of the amendment or waiver on our website.

Audit Committee and Audit Committee Financial Expert

We have a separately designated standing Audit Committee established in accordance with Section 3(a)(58)(A) of the Exchange Act. The Audit Committee is currently composed of three directors: Mr. Milano, Dr. Gowen and Mr. Molineaux. Mr. Milano currently serves as the chair of the Audit Committee.

The Board reviews the Nasdaq listing standards definition of independence for Audit Committee members on an annual basis and has determined that all members of the Company's Audit Committee are independent (as independence is currently defined in Rule 5605(c)(2)(A)(i) and (ii) of the Nasdaq listing standards and under Rule 10A-3 under the Exchange Act).

The Board has also determined that Mr. Milano qualifies as an "audit committee financial expert," as defined in applicable SEC rules. The Board made a qualitative assessment of Mr. Milano's level of knowledge and experience based

on a number of factors, including his formal education and experience as both a chief executive officer and chief financial officer for public reporting companies.

Insider Trading Policy and Prohibition on Hedging and Pledging

We have an Insider Trading Policy that is intended to ensure compliance with applicable securities laws and regulations by our officers, directors, and employees. This policy prohibits, among other things, trading in our common stock that would violate these laws and regulations, and it also imposes other restrictions such as trading blackout periods and prior notification and/or pre-clearance requirements for trading intended to protect against inadvertent violations of these laws and regulations. Pursuant to the policy, our company must also comply with applicable laws and regulations relating to insider trading when engaging in transactions in our securities. This policy also prohibits directors, officers, and other employees from engaging in short sales, transactions in put or call options, hedging transactions, margin accounts, pledging or other inherently speculative transactions with respect to our stock at any time. The policy is filed as an exhibit to this Annual Report.

Item 11. Executive Compensation

For the year ended December 31, 2024, our named executive officers (“NEOs”) were:

Name	Position
Neal Walker	Interim Chief Executive Officer ⁽¹⁾
Douglas Manion	Former Chief Executive Officer and President ⁽²⁾
Hugh Davis	President and Chief Operating Officer ⁽³⁾
Kevin Balthaser	Chief Financial Officer

- (1) Dr. Walker was appointed as our Interim Chief Executive Officer and President effective January 17, 2024, and served as President until November 18, 2024. In February 2025, he was appointed as our Chief Executive Officer.
- (2) Dr. Manion stepped down as Chief Executive Officer and President and ceased employment with us effective January 16, 2024.
- (3) Dr. Davis joined our Company as President and Chief Operating Officer effective November 18, 2024.

Summary Compensation Table

The following table presents the compensation awarded to or earned by each of our NEOs for the years ended December 31, 2024 and 2023.

Name and Principal Position	Year	Salary (\$)	Bonus	Stock Awards (\$)⁽¹⁾	Option Awards (\$)⁽¹⁾	Non-Equity Incentive Plan Compensation (\$)⁽²⁾	All Other Compensation (\$)	Total (\$)
Neal Walker ⁽³⁾ Interim Chief Executive Officer	2024	477,431	—	170,400	421,586	372,396	3,322 ⁽⁴⁾	1,445,135
Douglas Manion ⁽⁵⁾ Former Chief Executive Officer and President	2024	27,083	—	—	—	—	828,998 ⁽⁶⁾	856,081
	2023	600,000	—	1,832,760	4,513,721	198,000	13,200 ⁽⁷⁾	7,157,681
Hugh Davis ⁽⁸⁾ President and Chief Operating Officer	2024	62,500	—	423,720	1,076,674	30,625	1,666 ⁽⁷⁾	1,595,185
Kevin Balthaser Chief Financial Officer	2024	444,000	—	247,800	179,003	217,560	13,800 ⁽⁷⁾	1,102,163
	2023	444,000	—	509,100	1,253,812	124,320	13,200 ⁽⁷⁾	2,344,432

- (1) The amounts reflect the full grant date fair value for RSU and stock option awards granted during the indicated year. The grant date fair value was computed in accordance with ASC Topic 718, *Compensation—Stock Compensation*. The assumptions we used in valuing stock options and restricted stock unit awards are described in “Item 8—Notes to Consolidated Financial Statements—Note 7”.

- (2) The amounts reflect the portion of each officer's target annual bonus paid based on the achievement of our corporate and individual goals, as applicable, which for 2024 are discussed further below under "Narrative to Summary Compensation Table—Annual Bonus (Non-Equity Incentive Plan Compensation)."
- (3) Dr. Walker's employment with us commenced in January 2024.
- (4) The amount consists of fees paid under our director compensation policy for his service as our Chair of the Board prior to Dr. Walker being appointed as our Interim Chief Executive Officer in January 2024.
- (5) Dr. Manion's employment with us ended in January 2024.
- (6) The amount consists of (i) \$3,115 in company matching contributions to Dr. Manion's 401(k) plan account, (ii) the following accrued payments in connection with his separation agreement entered into in February 2024: (a) \$600,000, representing 12 months' base salary and (b) \$198,000, representing 100% of his 2023 target bonus, and (iii) \$27,883, representing accrued but unused vacation time paid out upon termination of his employment.
- (7) The amount consists of company matching contributions to the executive's 401(k) plan account.
- (8) Dr. Davis's employment with us commenced in November 2024.

Narrative to Summary Compensation Table

In setting NEO compensation, we consider compensation for comparable positions in the market, the historical compensation levels of our executives, individual performance as compared to our expectations and objectives, our desire to motivate our employees to achieve short- and long-term results that are in the best interests of our stockholders and a long-term commitment to our company. We do not target a specific competitive position or a specific mix of compensation among base salary, bonus or long-term incentives; however, we do deliver a majority of compensation through long-term incentives.

We review compensation annually for our NEOs, and in some cases more frequently as deemed appropriate. The various roles that contribute to our decisions and actions each year are as follows:

The Compensation Committee. The Compensation Committee is responsible for establishing and overseeing our executive compensation program. Our Compensation Committee typically reviews and discusses management's proposed compensation with the Chief Executive Officer for all executives other than the Chief Executive Officer. Based on those discussions and its discretion, the Compensation Committee then recommends the compensation for each NEO. Our Compensation Committee, without members of management present, discusses and ultimately approves the compensation of our executive officers.

Role of our Chief Executive Officer and other Management Members. Our Chief Executive Officer evaluates and reviews with the Compensation Committee the individual performance and contributions of each of the other NEOs and makes recommendations to the Compensation Committee regarding base salary, and short- and long-term incentive awards. The Compensation Committee reviews and considers such recommendations, but ultimately retains full discretion and authority over the final compensation decisions for the NEOs. Our Chief Executive Officer also recommends the Company performance objectives that are used to determine bonus amounts and consults with select members of management in the development of the goals. The Compensation Committee may request that certain executives attend portions of Compensation Committee meetings based on the topics being covered and their respective areas of expertise. NEO compensation decisions are made in executive session without the respective NEOs present.

Role of our Independent Compensation Consultant. In 2024, the Compensation Committee retained Pearl Meyer, a compensation consulting firm, to evaluate and make recommendations with respect to our executive compensation program. Pearl Meyer's role included assisting the Compensation Committee with the selection of a peer group of companies for comparison purposes, an analysis of our existing executive compensation, the design of our long-term incentive program, an analysis of our director compensation policy, sharing new developments in areas that fall within the Compensation Committee's jurisdiction, and otherwise advising the Compensation Committee as appropriate. The consultant serves at the pleasure of the Compensation Committee, and the consultant's fees are approved by the

Compensation Committee.

Annual Base Salary

The following table presents the annual base salaries for each of our NEOs for 2023 and 2024:

Name	Annual Base Salary (\$)		Percentage Change
	2023	2024	
Neal Walker	—	500,000	n/a
Douglas Manion	600,000	600,000	— %
Hugh Davis	—	500,000	n/a
Kevin Balthaser	444,000	444,000	— %

Annual Bonus (Non-Equity Incentive Plan Compensation)

We seek to motivate and reward our executives for achievements relative to our corporate goals and expectations and individual goals, if any, for each fiscal year. For 2024, the target bonus for Dr. Walker was 60% of his base salary and the target bonus for Dr. Davis and Mr. Balthaser was 40% of their respective base salaries.

The actual annual bonus paid is calculated by multiplying the NEO's annual base salary, target bonus percentage, the percentage attainment of the corporate goals established by the Board for such year, and for our NEOs other than the Chief Executive Officer, the percentage attainment of the individual goals established by our Chief Executive Officer. Given his interim role, the Compensation Committee established individual objectives for Dr. Walker in 2024. The Compensation Committee is not required to determine bonuses based on this exact formula and reserves the right to consider other factors and adjust bonus amounts accordingly.

For 2024, the bonus funding factor was weighted 75% for corporate goals and 25% for individual goals for all NEOs other than our Chief Executive Officer, whose bonus funding was 100% dependent on the achievement of individual goals.

The Compensation Committee reviews our performance against our goals and approves the extent to which we achieved each of our corporate goals and, with the input of our Chief Executive Officer, individual performance, as applicable, and, for each NEO, the amount of the bonus awarded.

In early 2024, our Compensation Committee approved our 2024 corporate performance goals. These goals were divided into two primary categories: (a) research and development, including advancement of our key assets, cost rationalization, and business development, including financing objectives and strategic planning (90%), and (b) other corporate activities, including legal, finance and compliance objectives (10%). In addition to the corporate performance goals described above, Dr. Walker evaluated the individual performance of each of Dr. Davis and Mr. Balthaser, and recommended a level of achievement to the Compensation Committee, and the Compensation Committee evaluated the individual performance of Dr. Walker. The individual goals for Dr. Davis and Mr. Balthaser focused on contributions toward our corporate objectives as well as the personal qualities necessary to effectively manage a team, solve problems and drive our business forward. Dr. Walker recommended full credit for these individual objectives, which the Compensation Committee approved. The individual goals for Dr. Walker focused on establishing and executing the strategic direction of the Company, as well as securing a permanent Chief Executive Officer.

In early 2025, the Compensation Committee considered each of the 2024 corporate performance goals, as well as individual goals where applicable, and awarded Dr. Walker, Dr. Davis and Mr. Balthaser 130%, 122.5% and 122.5% of their target bonuses, respectively, for the year ended December 31, 2024. The actual bonus amounts paid are reflected in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

Long-term Incentives

Long-term incentives represent a key element of our overall compensation program. This compensation element is primarily used to aid in attracting and retaining the talent we need to achieve our mission, strategies, and underlying corporate goals. Additionally, long-term incentives align the interests of our NEOs with our stockholders.

The Compensation Committee typically approves long-term incentive grants for NEOs at the start of their employment, and annually thereafter in connection with the annual performance review. Additionally, the Compensation Committee may periodically grant additional equity awards based on changes in job responsibility, performance and contribution, or other special circumstances.

In determining annual long-term incentive grants for NEOs, the Compensation Committee reviews market data for annual long-term incentive grant levels and groups the NEOs accordingly. The market data that the Compensation Committee reviewed for the purpose of sizing equity grants included long-term incentive awards expressed as a percentage of shares of common stock outstanding, as well as grant date fair values.

As part of his employment as the Interim Chief Executive Officer, in February 2024 the Compensation Committee awarded Dr. Walker options to purchase 497,000 shares of common stock with an exercise price of \$1.20, and 142,000 RSUs, in each case which vest monthly over 15 months commencing March 1, 2024 subject to his continuous service as the Interim Chief Executive Officer to the Company as of each such vesting date, provided that in the event he ceases to be Interim Chief Executive Officer but continues to provide continuous service in any capacity, such awards will continue to vest in the event that the Board determines in its sole discretion that he achieved the individual performance goals as defined in his letter agreement of employment as Interim Chief Executive Officer prior to the cessation of his employment as Interim Chief Executive Officer. In February 2024, for his annual long-term incentive award, the Compensation Committee awarded Mr. Balthaser options to purchase 206,500 shares of common stock with an exercise price of \$1.20, and 59,000 RSUs, in each case which vest or have vested in four equal installments on February 1, 2025, February 1, 2026, February 1, 2027 and February 1, 2028, subject to his continuous service as of the applicable vesting date. In addition, also in February 2024, Mr. Balthaser received a special one-time retention equity grant of 147,500 RSUs, which vests or has vested in two equal installments on December 31, 2024 and December 31, 2025, subject to his continuous service as of the applicable vesting date. The retention program was designed to retain employees needed to support the Company following the Company's reduction in force and announcement of the strategic review of its business. As part of his employment as the President and Chief Operating Officer, in December 2024 the Compensation Committee awarded Dr. Davis options to purchase 375,000 shares of common stock with an exercise price of \$3.96, and 107,000 RSUs, in each case which vest in four equal installments on December 2, 2025, December 2, 2026, December 2, 2027 and December 2, 2028, subject to his continuous service as of the applicable vesting date.

Severance Benefits

In February 2024, in connection with Dr. Manion's departure from the Company, we entered into a separation agreement, waiver and release with Dr. Manion pursuant to which we agreed to provide him the same severance benefits as if he were terminated without cause under his employment agreement as described below under "Additional Narrative Disclosure—Potential Payments upon Termination of Employment or upon Change in Control—Employment Agreements."

Clawback Policy

In October 2023, in order to comply with SEC rules promulgated under Section 10D-1 of the Exchange Act and Nasdaq listing standards, the Compensation Committee adopted and recommended to the Board the Company's Incentive Compensation Recoupment Policy, which the Board adopted in November 2023. Under the Incentive Compensation Recoupment Policy, in the event of an accounting restatement, the Compensation Committee, as the committee of the Board responsible for administering the policy, is authorized to recover certain incentive-based compensation paid to an executive officer of the Company on or after October 2, 2023 to the extent such incentive-based compensation was erroneously paid on the basis of financial results in respect of any of our three most recently completed fiscal years preceding the restatement.

Additionally, as a public company, if we are required to restate our financial results due to our material noncompliance with any financial reporting requirements under the federal securities laws as a result of misconduct, the Chief Executive Officer and Chief Financial Officer may be legally required to reimburse our Company for any bonus or other incentive-based or equity-based compensation they receive in accordance with the provisions of section 304 of the Sarbanes-Oxley Act of 2002.

Outstanding Equity Awards as of December 31, 2024

The following table provides information about outstanding equity awards held by each of our NEOs as of December 31, 2024. Dr. Manion did not have any outstanding equity awards as of December 31, 2024.

Name	Type of Award	Option Awards				Stock Awards	
		Number of Securities Underlying Unexercised Options (#)		Option Exercise Price (\$)	Option Expiration Date	Number of Shares of Stock That Have Not Vested (#)	Market Value of Shares of Stock That Have Not Vested (\$) ⁽⁸⁾
		Exercisable	Unexercisable				
Neal Walker	Option	211,019	—	10.66	8/31/2025		
	Option	137,335		28.68	12/17/2025		
	Option	145,600		28.92	12/14/2026		
	Option	151,200		22.09	1/31/2028		
	Option	255,552		1.26	3/1/2030		
	Option	191,850	—	24.06	2/28/2031		
	Option	168,050	—	14.94	3/1/2032		
	Option	331,333	165,667 ⁽¹⁾	1.20	1/31/2034		
	RSU					47,334 ⁽¹⁾	117,388
Hugh Davis	Option	—	375,000 ⁽²⁾	3.96	12/1/2034		
	RSU					107,000 ⁽²⁾	265,360
Kevin Balthaser	Option	11,200	—	27.54	7/4/2027		
	Option	2,100	—	22.09	1/31/2028		
	Option	11,625	3,875 ⁽³⁾	24.06	2/28/2031		
	Option	16,700	16,700 ⁽⁴⁾	14.94	2/29/2032		
	Option	26,250	78,750 ⁽⁵⁾	16.97	1/31/2033		
	Option		206,500 ⁽⁶⁾	1.20	1/31/2034		
	RSU						
	RSU					1,100 ⁽³⁾	2,728
	RSU					4,750 ⁽⁴⁾	11,780
	RSU					22,500 ⁽⁵⁾	55,800
	RSU					59,000 ⁽⁶⁾	146,320
	RSU					73,750 ⁽⁷⁾	182,900

- (1) Of the unvested stock options and RSUs, 33,133 and 33,134 stock options vested on January 1, 2025 and February 1, 2025, respectively, and 9,467 RSUs vested on each of January 1, 2025 and February 1, 2025. The remainder will vest in monthly installments through May 1, 2025, subject to the officer's continued service through each applicable vesting date.
- (2) These unvested stock options and RSUs will vest in four equal installments on December 2, 2025, December 2, 2026, December 2, 2027 and December 2, 2028, subject to the officer's continued service through each applicable vesting date.
- (3) These unvested stock options and RSUs will vest on March 1, 2025, subject to the officer's continued service through the vesting date.
- (4) These unvested stock options and RSUs will vest in two equal installments on March 1, 2025 and March 1, 2026, subject to the officer's continued service through each applicable vesting date.
- (5) Of the unvested stock options and RSUs, one-fourth vested on February 1, 2025 and the remainder will vest in two equal installments on February 1, 2026 and February 1, 2027, subject to the officer's continued service through each applicable vesting date.
- (6) Of the unvested stock options and RSUs, one-fourth vested on February 1, 2025 and the remainder will vest in three equal installments on February 1, 2026, February 1, 2027 and February 1, 2028, subject to the officer's continued service through each applicable vesting date.
- (7) The remainder of the unvested RSUs will vest on December 31, 2025.

(8) Based on the closing price of our common stock of \$2.48 per share on December 31, 2024.

Additional Narrative Disclosure

Potential Payments upon Termination of Employment or upon Change in Control

Employment Agreements

We have entered into employment agreements with each of Dr. Davis and Mr. Balthaser, and had entered into an employment agreement with Dr. Manion prior to his departure in January 2024. We entered into a letter agreement with Dr. Walker in connection with his appointment as our Interim Chief Executive Officer in January 2024 (which is described below). In connection with his appointment as our Chief Executive Officer, we entered into an employment agreement with Dr. Walker in February 2025. Under the employment agreements, each of them is (or, in the case of Dr. Manion, was) eligible to receive severance benefits in the specified circumstances, as applicable.

Severance Upon Qualifying Termination Unrelated to a Change of Control

Each employment agreement provides for payments in the event the executive's employment is terminated due to death or "Disability", in the event we terminate the executive's employment "Without Cause," if the executive resigns for "Good Reason" (each as defined below), or if the executive's employment is terminated upon non-renewal of the agreement by the Company, provided that the executive executes and does not revoke a release of claims (each, a "Qualifying Termination").

In the event of a Qualifying Termination, each executive would receive the following severance benefits:

- continued payment of then-current base salary for a period of 12 months following termination, in each case payable in accordance with our normal payroll practices;
- a lump-sum payment of any approved but unpaid bonuses or portion thereof for the preceding year or the year of termination for Dr. Davis, Mr. Balthaser and Dr. Manion, and payment of any bonuses for the preceding year for which he remains employed through the last day of such year for Dr. Walker; and
- a direct payment by the Company to the applicable healthcare provider of the Company's portion of the medical, vision and dental coverage premiums to maintain any COBRA coverage for which he or she is eligible and has appropriately elected for a period of 12 months following termination.

Severance Upon Qualifying Termination Related to a Change of Control

In the event of a Qualifying Termination (other than if the executive's employment is terminated upon non-renewal by the Company) on or within three months prior to, or within 12 months following, a "Change of Control" (as defined below), each executive would receive the following severance benefits:

- continued payment of then-current base salary for a period of 18 months following termination for Dr. Manion and Dr. Walker and for a period of 12 months following termination for each of the other NEOs, payable in accordance with our normal payroll practices;
- a lump-sum payment of any approved but unpaid bonuses or portion thereof for the preceding year or the year of termination for Dr. Davis, Mr. Balthaser and Dr. Manion, and payment of any bonuses for the preceding year for which he remains employed through the last day of such year for Dr. Walker;
- an additional lump sum payment equal to 150% of the target bonus for Dr. Manion and Dr. Walker and 100% of the target bonus for each of the other NEOs;
- a direct payment by the Company to the applicable healthcare provider of the Company's portion of the medical, vision and dental coverage premiums to maintain any COBRA coverage for which he is eligible

and has appropriately elected for a period of 18 months following termination for Dr. Manion and Dr. Walker and for a period of 12 months following termination for each of the other NEOs; and

- if the termination occurs on or within three months prior to the Change of Control, all of his unvested stock options and other equity awards outstanding on the effective date of termination would become fully vested on the effective date of the Change of Control, or if the termination occurs within 12 months following the effective date of the Change of Control (provided that any surviving corporation or acquiring corporation assumes his stock options or other equity awards, as applicable, or substitutes similar stock options or equity awards for his stock options or equity awards, as applicable, in accordance with the terms of the applicable equity incentive plans), all unvested stock options and other equity awards outstanding on the effective date of termination would become fully vested on the date of termination.

Definitions

With respect to each of our NEOs, the following definitions were adopted in their employment agreements:

- “Cause” means: (i) his conviction of, or guilty plea to, a felony, other than traffic violations; (ii) any act or omission by him or her which constitutes gross negligence or a material breach of his duty of loyalty; (iii) any material breach by him or her of our personnel policies; (iv) refusal to follow or implement a clear and reasonable directive; (v) breach of fiduciary duty; or (vi) a material violation or breach by him or her of his employment agreement, other than an event described in the foregoing clauses, or any other agreement with us;
- “Good Reason” means, in the absence of events that would support a termination for cause: (i) there is a material failure by us or our successor to pay his salary or additional compensation or benefits in accordance with the employment agreement; (ii) his annual base salary is materially decreased without his prior written consent; (iii) he or she is assigned duties materially inconsistent with his title and the responsibilities set forth in his job description without his prior written consent; (iv) his place of employment is changed to a location that is greater than 50 miles from his current place of employment (disregarding for this purpose any remote work arrangements); or (v) any other material violation or breach by us of his employment agreement; provided, however, none of the above events will constitute good reason absent him or her providing us with proper notice and our failure to cure such event within 30 days of such notice; and
- “Change of Control” means: (i) our consolidation or merger with or into any other corporation or other entity or person, or any other corporate reorganization, in which our stockholders immediately prior to such consolidation, merger or reorganization own, in the aggregate, less than 50% of the surviving entity’s voting power or outstanding capital stock immediately after such consolidation, merger or reorganization, or any transaction or series of related transactions to which we, or any of our stockholders is a party in which greater than 50% of our voting power or outstanding capital stock is transferred, or pursuant to which any person or group of affiliated persons obtains greater than 50% of our voting power or outstanding capital stock, excluding any consolidation or merger effected exclusively to change our domicile; or (ii) any sale, license or other disposition, including through a division or spin-off transaction, of all or substantially all of our assets or any of our subsidiaries’ assets or any sale, exclusive license or other disposition of all or substantially all of our intellectual property; provided, however that neither of the following constitutes 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 our other existing stockholders; or (B) issuances of our equity securities 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 the Company as defined in Section 409A of the Code (“Section 409A”) or a change in the ownership of a substantial portion of our assets as defined in Section 409A, as the case may be.

Letter Agreement with Dr. Walker

In January 2024, in connection with his appointment as Interim Chief Executive Officer, we entered into a letter agreement with Dr. Walker setting forth the terms of his employment. As described above under “Narrative to Summary Compensation Table—Long-Term Incentives”, Dr. Walker was granted equity awards in connection with his appointment. The equity awards will accelerate vesting and exercisability in full upon a Change in Control (as defined in the Company’s 2015 Equity Incentive Plan (“2015 Plan”)).

Separation Agreement with Dr. Manion

As described above, in January 2024, Dr. Manion departed the Company following which we entered into a separation agreement, waiver and release with Dr. Manion pursuant to which we agreed to provide him the same severance benefits as if he were terminated without cause unrelated to a Change of Control under his employment agreement.

Benefits

We maintain a tax-qualified retirement plan (our 401(k) plan) that provides eligible U.S. employees with an opportunity to save for retirement on a tax advantaged basis, up to limits prescribed by applicable law. Currently, we match each eligible employee’s contributions up to 4% of total eligible compensation. Employees are immediately and fully vested in their contributions and our matching contribution.

Our NEOs are eligible to participate in all benefit plans offered to our employees, including our medical, dental, vision, group life and disability insurance plans. Our NEOs accrue more vacation time each pay period than other employees. We do not otherwise provide perquisites or personal benefits to our NEOs.

Non-Employee Director Compensation

Under our non-employee director compensation policy, we pay each of our non-employee directors a cash retainer for service on the Board and for service on each committee of which the director is a member. The policy applies to each of our directors who is not an employee of our company. During 2024, Dr. Manion and Dr. Davis, as employees of our Company, did not receive any additional compensation for service as a director. Effective January 17, 2024, Dr. Walker was appointed as our Interim Chief Executive Officer and stopped receiving additional compensation for service as a director.

Pursuant to the policy in effect for 2024, each non-employee director received an annual cash retainer of \$40,000 for serving on our Board. The Chair of the Board received an additional annual cash retainer of \$30,000 and the Lead Independent Director received an additional annual cash retainer of \$25,000. The members of each of the Audit, Compensation, Nominating and Corporate Governance and Research and Development Committees received additional retainers for such service, as did the Chair of each such committee (in addition to the member retainers), as follows:

Committee	Member Annual Service Retainer (\$)	Additional Chair Annual Service Retainer (\$)
Audit Committee	7,500	12,500
Compensation Committee	7,500	12,500
Nominating and Corporate Governance Committee	4,500	4,500
Research and Development Committee ⁽¹⁾	6,000	8,000

(1) Effective December 31, 2024, the Research and Development Committee was dissolved.

All annual cash compensation amounts were payable in equal quarterly installments in arrears, on the last day of each fiscal quarter for which the service occurred, prorated based on the days served in the applicable fiscal quarter.

We also reimbursed our non-employee directors for reasonable travel and out-of-pocket expenses incurred in connection with attending our Board and committee meetings.

Each new non-employee director who joins our Board will be granted awards under our 2015 Plan with an aggregate grant date fair value (as calculated for financial reporting purposes) equal to the lesser of (a) \$320,000 or (b) the fair value of 22,500 stock options measured as of the date the director joins the Board. Once the aggregate fair value of the new director award has been determined, the new director will be granted a stock option having a grant date fair value equal to 70% of such amount and RSUs having a grant date fair value equal to 30% of such amount.

On the date of each annual meeting of our stockholders, each non-employee director who continues to serve as a director of our company following the meeting will be granted awards under our 2015 Plan with an aggregate grant date fair value (as calculated for financial reporting purposes) equal to the lesser of (a) \$320,000 or (b) the fair value of 22,500 stock options measured as of the annual meeting date. Once the aggregate fair value of the continuing director award has been determined, the continuing director will be granted a stock option having a grant date fair value equal to 70% of such amount and RSUs having a grant date fair value equal to 30% of such amount. In no event, however, shall the fair value of the annual award, together with the fair value of any initial award granted to a new director who joined the Board in the same fiscal year, exceed \$320,000 in the aggregate.

The shares subject to each stock option granted will vest in equal monthly installments over 12 months and the RSUs will vest in one installment on the first anniversary of the grant date, subject to continued service through the applicable vesting date. The exercise price per share of each stock option will be equal to the closing price of our common stock on the date of the option grant. Each such stock option will have a term of ten years from the date of grant, subject to earlier termination in connection with a termination of the non-employee director's continuous service with us.

On June 6, 2024, the date of our 2024 annual meeting of stockholders, each non-employee director then serving on our Board (other than Dr. Walker) who continued to serve as a director of our company following the meeting was granted a stock option to purchase 15,750 shares of common stock and 4,793 RSUs under our 2015 Plan. These awards are reflected in the table below.

Director Compensation Table

The following table shows the compensation earned by each of our non-employee directors for 2024. During 2024, Dr. Manion and Dr. Davis, as employees of our Company, did not receive any additional compensation for service as a director. Effective January 17, 2024, Dr. Walker was appointed as our Interim Chief Executive Officer and stopped receiving additional compensation for service as a director. Dr. Manion's, Dr. Davis' and Dr. Walker's compensation as an executive officer is set forth above under "Summary Compensation Table."

Name	Fees Earned or Paid in Cash (\$)	Stock Awards (\$) ⁽¹⁾⁽²⁾⁽³⁾	Option Awards (\$) ⁽¹⁾⁽²⁾⁽⁴⁾	Total (\$)
William Humphries	50,125	4,937	11,505	66,567
Anand Mehra, M.D.	70,875	4,937	11,505	87,317
Christopher Molineaux	79,625	4,937	11,505	96,067
Andrew Powell ⁽⁵⁾	20,363	—	—	20,363
Bryan Reasons ⁽⁶⁾	22,363	—	—	22,363
Andrew Schiff, M.D.	47,875	4,937	11,505	64,317
Maxine Gowen, Ph.D.	54,000	4,937	11,505	70,442
Vincent Milano	56,875	4,937	11,505	73,317

(1) Reflects the aggregate grant date fair value for awards granted for the fiscal year ended December 31, 2024 calculated in accordance with FASB ASC Topic 718. For a discussion of valuation assumptions, see "Item 8—Notes to Consolidated Financial Statements—Note 7." Our directors will not realize the estimated value of these awards until the awards are vested, exercised and/or sold, as applicable.

(2) As of December 31, 2024, our non-employee directors held the following number of stock options and RSUs: Mr. Humphries, 94,125 stock options and 4,793 RSUs; Dr. Mehra, 76,125 stock options and 4,793 RSUs; Mr. Molineaux,

84,401 stock options and 4,793 RSUs; Dr. Schiff, 92,125 stock options and 4,793 RSUs; Dr. Gowen, 84,125 stock options and 4,793 RSUs; and Mr. Milano, 90,125 stock options and 4,793 RSUs.

- (3) Consists of 4,793 RSUs granted on June 6, 2024. The RSUs will vest on June 6, 2025, subject to continuous service with us through that date.
- (4) Consists of an option granted on June 6, 2024 to purchase 15,750 shares at an exercise price of \$1.03 per share. This option vests in 12 equal monthly installments through June 6, 2025, subject to continuous service with us through each vesting date.
- (5) Mr. Powell resigned effective as of the 2024 annual meeting and therefore did not receive an annual equity award.
- (6) Mr. Reasons did not stand for re-election at the 2024 annual meeting when his term expired and therefore did not receive an annual equity award.

Policies and Practices Related to the Grant of Certain Equity Awards Close in Time to the Release of Material Nonpublic Information

From time to time, we grant equity awards, including stock options, to our employees, including our NEOs. Our typical practice is to grant employee stock options on the first business day of the month following the month in which the options are approved (or on the same day of approval if such approval is on the first business day of a month). We typically grant annual refresh employee option grants in the first quarter of each fiscal year, which refresh grants are typically approved at a regularly scheduled meeting of the Compensation Committee occurring in such quarter. In addition, non-employee directors receive automatic grants of initial and annual stock option awards, at the time of a director's initial appointment or election to the board and at the time of each annual meeting of our stockholders, respectively, pursuant to our non-employee director compensation policy, as further described under the heading, "Non-Employee Director Compensation". We do not otherwise maintain any written policies on the timing of awards of stock options, stock appreciation rights, or similar instruments with option-like features. The Compensation Committee considers whether there is any material nonpublic information ("MNPI") about our company when determining the timing of stock option grants and it does not seek to time the award of stock options in relation to the Company's public disclosure of MNPI. We have not timed the release of MNPI for the purpose of affecting the value of executive compensation.

The following table is being provided pursuant to Item 402(x)(2) of Regulation S-K.

Name (a)	Grant date (b)	Number of securities underlying the award (c)	Exercise price of the award (\$/Sh) (d)	Grant date fair value of the award (e)	Percentage change in the closing market price of the securities underlying the award between the trading day ending immediately prior to the disclosure of material nonpublic information and the trading day beginning immediately following the disclosure of material nonpublic information (f) ⁽¹⁾
Neal Walker	February 1, 2024	497,000	\$ 1.20	\$ 421,586	(5.8)%
Kevin Balthaser	February 1, 2024	206,500	\$ 1.20	\$ 179,003	(5.8)%

- (1) The option grants reported in this table were made two business days before the Company filed (i) a Form 8-K under Item 5.02 reporting the departure of our Chief Medical Officer, the entry into an amended and restated employment agreement with our Chief Scientific Officer, and the entry into a separation agreement with our former Chief Executive Officer and President following his previously reported departure and (ii) a Form 8-K amendment under Item 5.02 reporting the entry into a compensatory letter agreement with Dr. Walker following his previously reported appointment as our Interim Chief Executive Officer.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information regarding the ownership of our common stock as of February 10, 2025 by: (i) each director; (ii) each of our NEOs; (iii) all currently serving executive officers and directors as a group; and (iv) all those known by us to be beneficial owners of more than five percent of our common stock.

Beneficial Owner ⁽¹⁾	Number of Shares Beneficially Owned	Percent of Shares Beneficially Owned
5% Stockholders:		
BML Investment Partners, L.P. ⁽²⁾	14,250,000	13.2 %
Biosion, Inc. ⁽³⁾	11,281,985	10.4
Adage Capital Management, L.P. ⁽⁴⁾	9,627,304	8.9
Entities associated with Vivo Capital LLC ⁽⁵⁾	8,888,888	8.2
Rock Springs Capital Management LP ⁽⁶⁾	6,761,861	6.3
Named Executive Officers and Directors:		
Neal Walker ⁽⁷⁾	3,204,123	2.9
Douglas Manion ⁽⁸⁾	41,813	*
Hugh Davis	—	—
Kevin Balthaser ⁽⁹⁾	251,310	*
William Humphries ⁽¹⁰⁾	128,107	*
Christopher Molineaux ⁽¹¹⁾	142,814	*
Anand Mehra ⁽¹²⁾	791,405	*
Andrew Schiff ⁽¹³⁾	540,997	*
Maxine Gowen ⁽¹⁴⁾	106,336	*
Vincent Milano ⁽¹⁵⁾	107,898	*
All current directors and executive officers as a group (11 persons) ⁽¹⁶⁾	6,179,434	5.6

* Less than one percent.

- (1) This table is based upon information supplied by officers, directors and principal stockholders and a review of Schedule 13G, Schedule 13D and Section 16 filings with the SEC. Unless otherwise indicated in the footnotes to this table and subject to community property laws where applicable, we believe that each of the stockholders named in this table has sole voting and investment power with respect to the shares indicated as beneficially owned. Applicable percentages are based on 108,148,298 shares outstanding on February 10, 2025, adjusted as required by rules promulgated by the SEC. Except as otherwise noted below, the principal business address of each of the executive officers and directors is c/o Aclaris Therapeutics, Inc., 701 Lee Road, Suite 103, Wayne, Pennsylvania 19087.
- (2) This information has been obtained from a Schedule 13G/A filed on February 13, 2025 by BML Investment Partners, L.P. (“BML”). The shares reported are held by BML. Braden M. Leonard is the managing member of BML Capital Management, LLC, the sole general partner of BML, and as a result, Mr. Leonard is deemed to be the indirect beneficial owner of the shares held directly by BML. The principal business address of BML is 65 E Cedar, Suite 2, Zionsville, IN 46077.
- (3) This information has been obtained from a Schedule 13G filed on November 25, 2024 by Biosion. The number represents 11,281,985 shares of common stock issuable to Biosion upon exercise of a warrant held by it. The principal business address of Biosion is 5th Floor, Building D, 3-1 Zhongdan Unit, South Longshan Rd, Jiangbei New District, Nanjing, Jiangsu, China.
- (4) This information has been obtained from a Schedule 13G filed on February 12, 2025 by Adage Capital Management, L.P. (“ACM”), Robert Atchinson, and Phillip Gross, which states that the shares are directly held by Adage Capital Partners, L.P. (“ACP”), of which ACM is the investment manager. Mr. Atchinson is (a)

managing member of Adage Capital Advisors, L.L.C. (“ACA”), the managing member of Adage Capital Partners GP, L.L.C., (“ACPGP”), the general partner of ACP and (b) managing member of Adage Capital Partners LLC, (“ACPLLC”), general partner of ACM. Mr. Gross is (a) managing member of ACA, managing member of ACPGP and (b) managing member of ACPLLC. The principal business address of this entity and persons is 200 Clarendon Street, 52nd Floor, Boston, Massachusetts 02116.

- (5) This information has been obtained from a Schedule 13G filed on November 21, 2024 by Vivo Opportunity Fund Holdings, L.P. (“Opportunity Fund”), Vivo Opportunity, LLC, Vivo Asia Opportunity Fund Holdings, L.P. (“Asia Opportunity Fund”), and Vivo Opportunity Cayman, LLC. Consists of (a) 7,955,160 shares of common stock held by Opportunity Fund and (b) 933,728 shares of common stock held by Asia Opportunity Fund. Vivo Opportunity, LLC is the general partner of Opportunity Fund. Vivo Opportunity Cayman, LLC is the general partner of Asia Opportunity Fund. The voting members of each of Vivo Opportunity, LLC and Vivo Opportunity Cayman, LLC are Kevin Dai, Gaurav Aggarwal, Frank Kung and Shan Fu, none of whom has individual voting or investment power with respect to the shares held by Opportunity Fund or Asia Opportunity Fund. The principal business address of these entities and persons is 192 Lytton Avenue, Palo Alto, California 94301.
- (6) This information has been obtained from a Schedule 13G filed on November 22, 2024 by Rock Springs Capital Management LP, Rock Springs Capital LLC, its general partner, and Rock Springs Capital Master Fund LP, which states that 5,697,000 shares are held directly by Rock Springs Capital Master Fund LP and 1,064,861 shares are held directly by Four Pines Master Fund LP. Rock Springs Capital Management LP serves as the investment manager to each of Rock Springs Capital Master Fund LP and Four Pines Master Fund LP. The principal business address of Rock Springs Capital Management LP and Rock Springs Capital LLC is 650 South Exeter St., Suite 1070, Baltimore, MD 21202. The principal business address of Rock Springs Capital Master Fund is c/o Walkers Corporate Limited, 190 Elgin Avenue, George Town, Grand Cayman, KY1-9008, Cayman Islands.
- (7) Consists of (a) 1,460,718 shares of common stock, (b) 1,724,472 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025 and (c) 18,933 shares of common stock underlying RSUs that will vest within 60 days of February 10, 2025.
- (8) Consists of 41,813 shares of common stock.
- (9) Consists of (a) 89,860 shares of common stock, (b) 157,975 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025 and (c) 3,475 shares of common stock underlying RSUs that will vest within 60 days of February 10, 2025.
- (10) Consists of (a) 28,732 shares of common stock and (b) 99,375 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025.
- (11) Consists of (a) 53,163 shares of common stock and (b) 89,651 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025.
- (12) Consists of (a) 710,030 shares of common stock and (b) 81,375 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025.
- (13) Consists of (a) 434,455 shares of common stock owned directly by Aisling Capital IV, LP (“Aisling”), (b) 9,167 shares of common stock owned directly by Dr. Schiff and (c) 97,375 shares of common stock underlying options held directly by Dr. Schiff that are exercisable within 60 days of February 10, 2025. The shares owned directly by Aisling are held indirectly by Aisling Capital Partners IV, LP (“Aisling GP”), as general partner of Aisling, Aisling Capital Partners IV, LLC (“Aisling Partners”), as general partner of Aisling GP, and each of the individual managing members of Aisling Partners. Dr. Schiff is one of the managing members of Aisling Partners and shares voting and dispositive power over the shares directly held by Aisling.
- (14) Consists of (a) 16,961 shares of common stock and (b) 89,375 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025.

(15) Consists of (a) 12,523 shares of common stock and (b) 95,375 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025.

(16) Consists of (a) 3,151,103 shares of common stock, (b) 2,944,998 shares of common stock underlying options that are exercisable within 60 days of February 10, 2025 and (c) 83,333 shares of common stock underlying RSUs that will vest within 60 days of February 10, 2025.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides certain information regarding our equity compensation plans in effect as of December 31, 2024:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders:			
2012 Equity Compensation Plan ⁽¹⁾	218,404	\$ 10.66	—
2015 Equity Incentive Plan	7,644,714	\$ 8.09 ⁽²⁾	4,820,283 ⁽³⁾
Equity compensation plans not approved by security holders:			
2017 Inducement Plan ⁽⁴⁾	329,000	\$ 24.61	—
2024 Inducement Plan ⁽⁵⁾	806,000	3.08 ⁽⁶⁾	1,194,000
Total	8,998,118		6,014,283

(1) No additional further options or awards may be granted under the 2012 Equity Compensation Plan.

(2) Weighted average exercise price for the 2015 Plan gives effect to outstanding restricted stock units, which have no exercise price. Excluding the restricted stock units, the weighted average exercise price would be \$11.15 per share.

(3) On January 1 of each year ended with January 1, 2025, the number of shares reserved under the 2015 Plan automatically increased by 4% of the total number of shares of common stock that were outstanding at that time, or a lesser number of shares as determined by our Board. Pursuant to the terms of the 2015 Plan, an additional 4,314,004 shares were added to the number of available shares reflected in the table effective January 1, 2025.

(4) Our Board adopted the 2017 Inducement Plan, which is a non-stockholder approved stock plan adopted pursuant to the “inducement exception” provided under Nasdaq listing rules. 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. No additional further options or awards may be granted under the 2017 Inducement Plan; all outstanding stock awards will continue to be governed by their existing terms.

(5) For a description of the material terms of this plan, see “Item 8—Notes to Consolidated Financial Statements—Note 7—2024 Inducement Plan.”

(6) Weighted average exercise price for the 2024 Inducement Plan gives effect to outstanding RSUs, which have no exercise price. Excluding the RSUs, the weighted average exercise price would be \$3.96 per share.

Item 13. Certain Relationships and Related Transactions, and Director Independence

Related Person Transactions Policy and Procedures

We have adopted a related person transactions policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we and any related person are, were or will be participants in which the amount involved exceeds \$120,000. Transactions involving compensation for services provided to us as an employee, consultant or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members, and any entity owned or controlled by such persons.

Under the policy, if a transaction has been identified as a related person transaction, including any transaction that was not a related person transaction when originally consummated or any transaction that was not initially identified as a related person transaction prior to consummation, our management must present information regarding the related person transaction to our Audit Committee, or, if Audit Committee approval would be inappropriate, to another independent body of our Board, for review, consideration and approval or ratification. The presentation must include a description of, among other things, the material facts, the interests, direct and indirect, of the related persons, the benefits to us of the transaction and whether the transaction is on terms that are comparable to the terms available to or from as the case may be, an unrelated third party or to or from employees generally. Under the policy, we collect information that we deem reasonably necessary from each director, executive officer and, to the extent feasible, significant stockholder to enable us to identify any existing or potential related person transactions and to effectuate the terms of the policy. In addition, under our Code of Business Conduct and Ethics, our employees and directors have an affirmative responsibility to disclose any potential conflicts of interest. In considering related person transactions, our Audit Committee, or other independent body of our Board, takes into account the relevant available facts and circumstances including, but not limited to:

- the risks, costs and benefits to us;
- the impact on a director's independence in the event that the related person is a director, immediate family member of a director or an entity with which a director is affiliated;
- the terms of the transaction;
- the availability of other sources for comparable services or products; and
- the terms available to or from, as the case may be, unrelated third parties or to or from employees generally.

The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our Audit Committee, or other independent body of our Board, must consider, in light of known circumstances, whether the transaction is in, or is not inconsistent with, our best interests and those of our stockholders, as our Audit Committee, or other independent body of our Board, determines in the good faith exercise of its discretion.

Certain Related Person Transactions

Except as described below, there have been no transactions since January 1, 2023 to which we have been a participant in which the amount involved exceeded or will exceed the lesser of (1) \$120,000 or (2) 1% of the average of our total assets for the last two completed fiscal years, and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or any members of their immediate family, had or will have a direct or indirect material interest, other than compensation arrangements which are described under "Executive Compensation" and "Non-Employee Director Compensation."

Participation in Private Placement

In November 2024, Anand Mehra, a member of our Board, purchased 666,666 shares of our common stock at a price per share of \$2.25 in connection with a private placement for an aggregate purchase price of \$1.5 million.

Indemnification Agreements

In addition to the compensation arrangements with our directors and executive officers, we have entered into indemnity agreements with each of them 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.

Director Independence

As required under the Nasdaq Stock Market (“Nasdaq”) listing standards, a majority of the members of a listed company’s board of directors must qualify as “independent,” as affirmatively determined by the Board. The Board consults with the Company’s counsel to ensure that the Board’s determinations are consistent with relevant securities and other laws and regulations regarding the definition of “independent,” including those set forth in pertinent listing standards of Nasdaq, as in effect from time to time.

Consistent with these considerations, after review of all relevant identified transactions or relationships between each director, or any of his or her family members, and our company, senior management and independent auditors, the Board has affirmatively determined that six of our eight current directors are independent directors within the meaning of the applicable Nasdaq listing standards: Mr. Humphries, Dr. Mehra, Mr. Molineaux, Dr. Schiff, Dr. Gowen and Mr. Milano. In addition, the Board also affirmatively determined that Andrew Powell and Byran Reasons, who served on the Board during a part of 2024, were also independent directors within the meaning of the applicable Nasdaq listing standards. In making these determinations, the Board found that none of these directors had a material or other disqualifying relationship with our company. Dr. Walker, as our Chief Executive Officer, and Dr. Davis, as our President and Chief Operating Officer, are not independent as a result of their employment by our company.

Item 14. Principal Accountant Fees and Services

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2024 and 2023 by PricewaterhouseCoopers LLP, our principal accountant.

	Fiscal Year Ended December 31,	
	2024	2023
Audit Fees	\$ 507,000	\$ 841,120

All audit fees were pre-approved by the Audit Committee.

Pre-Approval Policies and Procedures

The Audit Committee has adopted a policy and procedures for the pre-approval of audit and non-audit services rendered by our independent registered public accounting firm, PricewaterhouseCoopers LLP. The policy generally pre-approves specified services in the defined categories of audit services, audit-related services and tax services up to specified amounts. Pre-approval may also be given as part of the Audit Committee’s approval of the scope of the engagement of the independent auditor or on an individual, explicit, case-by-case basis before the independent auditor is engaged to provide each service. The pre-approval of services may be delegated to one or more of the Audit Committee’s members, but the decision must be reported to the full Audit Committee at its next scheduled meeting.

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).
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	Certificate of Amendment to Amended and Restated Certificate of Incorporation of the Registrant (incorporated herein by reference to Exhibit 3.2 to the Registrant’s Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on August 7, 2023).
3.3	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	Description of Securities. (incorporated by reference to Exhibit 4.1 to the Registrant’s Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
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+ 2017 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 2017 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+ 2024 Inducement Plan (incorporated herein by reference to Exhibit 10.4 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on November 18, 2024).
- 10.11+ Form of Stock Option Grant Notice and Stock Option Agreement used in connection with the 2024 Inducement Plan (incorporated herein by reference to Exhibit 10.5 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on November 18, 2024).
- 10.12+ Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement used in connection with the 2024 Inducement Plan (incorporated herein by reference to Exhibit 10.6 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on November 18, 2024).
- 10.13+ Ninth Amended and Restated Non-Employee Director Compensation Policy (incorporated herein by reference to Exhibit 10.4 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 8, 2023).
- 10.14+ 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).
- 10.15+ Second Amended and Restated Employment Agreement, effective as of February 1, 2024, by and between the Registrant and Joseph Monahan (incorporated herein by reference to Exhibit 10.15 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
- 10.16+ Employment Agreement, dated as of January 31, 2022, by and between the Registrant and James Loerop (incorporated herein by reference to Exhibit 10.16 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 24, 2022).
- 10.17+ Separation Agreement, Waiver, and Release, dated as of February 4, 2024, by and between the Registrant and Douglas Manion (incorporated herein by reference to Exhibit 10.18 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
- 10.18+ Employment Agreement, dated as of January 1, 2023, by and between the Registrant and Kevin Balthaser (incorporated herein by reference to Exhibit 10.24 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 23, 2023).
- 10.19+ Amended and Restated Employment Agreement, dated as of January 1, 2023, by and between the Registrant and Douglas Manion (incorporated herein by reference to Exhibit 10.23 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 23, 2023).
- 10.20+ Letter Agreement, dated as of January 31, 2024, by and between the Registrant and Neal Walker (incorporated herein by reference to Exhibit 10.22 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
- 10.21*§+ Employment Agreement, dated as of February 26, 2025, by and between the Registrant and Neal Walker.
- 10.22+ Employment Agreement, dated as of November 18, 2024, by and between the Registrant and Hugh Davis (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 November 18, 2024).
- 10.23^ Office Lease, dated May 26, 2023, by and between the Registrant and CBCC – Lee Road Acquisitions, LLC (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 June 1, 2023).
- 10.24* Amended and Restated Sales Agreement, dated February 27, 2025, by and among the Registrant, Leerink Partners LLC and Cantor Fitzgerald & Co.
- 10.25^ Royalty Purchase Agreement, effective as of July 16, 2024, by and between the Registrant and OCM IP Healthcare Portfolio LP (incorporated herein by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on August 7, 2024).
- 10.26*^§ Exclusive License Agreement, dated as of November 18, 2024, by and between the Registrant and Biosion, Inc.
- 10.27*^§ Collaboration Agreement, dated as of November 18, 2024, by and among the Registrant, Biosion, Inc. and Chia Tai Tianqing Pharmaceutical Group, Co., Ltd.
- 10.28*^§ Form of Common Stock Purchase Warrant Agreement issued on November 18, 2024.

10.29	Form of Securities Purchase Agreement, dated November 18, 2024, by and between the Registrant and the investors named therein (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 November 18, 2024).
10.30	Form of Registration Rights Agreement, dated November 18, 2024, by and between the Registrant and the investors named therein (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 November 18, 2024).
19.1*	Insider Trading Policy, effective as of February 26, 2025.
21.1	Subsidiaries of the Registrant (incorporated herein by reference to Exhibit 21.1 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
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.
97.1	Aclaris Therapeutics, Inc. Incentive Compensation Recoupment Policy, adopted as of October 2, 2023 (incorporated herein by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2024).
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 is 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(b)(10)(iv) of Regulation S-K promulgated by the SEC, certain portions of this exhibit have been redacted because the Company has determined that the information is both not material and is the type that the Company treats as private or confidential. The Company hereby agrees to furnish supplementally to the SEC, upon its request, an unredacted copy of the exhibit.

§ 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.

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.

Date: February 27, 2025

By: /s/ Neal Walker

Neal Walker
Chief Executive Officer

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Neal Walker and Kevin Balthaser, 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
<u>/s/ Neal Walker</u> Neal Walker	Chief Executive Officer, and Chairman of the Board of Directors <i>(Principal Executive Officer)</i>	February 27, 2025
<u>/s/ Kevin Balthaser</u> Kevin Balthaser	Chief Financial Officer <i>(Principal Financial Officer and Principal Accounting Officer)</i>	February 27, 2025
<u>/s/ Christopher Molineaux</u> Christopher Molineaux	Lead Independent Director	February 27, 2025
<u>/s/ Anand Mehra, M.D.</u> Anand Mehra, M.D.	Director	February 27, 2025
<u>/s/ William Humphries</u> William Humphries	Director	February 27, 2025
<u>/s/ Andrew Schiff</u> Andrew Schiff	Director	February 27, 2025
<u>/s/ Hugh Davis</u> Hugh Davis	President, Chief Operating Officer and Director	February 27, 2025
<u>/s/ Maxine Gowen</u> Maxine Gowen	Director	February 27, 2025
<u>/s/ Vincent Milano</u> Vincent Milano	Director	February 27, 2025



DIRECTORS

Dr. Neal Walker

Chair, Chief Executive Officer

Christopher P. Molineaux

Lead Independent Director

Hugh Davis, Ph.D.

Director, President and Chief Operating Officer

Maxine Gowen, Ph.D.

Director

William Humphries

Director

Anand Mehra, M.D.

Director

Vincent Milano

Director

Andrew Schiff, M.D.

Director

OFFICERS

Dr. Neal Walker

Chief Executive Officer

Hugh Davis, Ph.D.

President and Chief Operating Officer

Kevin Balthaser

Chief Financial Officer

Joseph Monahan, Ph.D.

Chief Scientific Officer

James Loerop

Chief Business Officer

STOCKHOLDER REFERENCE

Annual Meeting

The annual meeting of stockholders will be held virtually at www.virtualshareholdermeeting.com/ACRS2025, at 9:00 a.m. Eastern Time on Thursday, June 5, 2025.

Registrar and Transfer Agent

Broadridge Corporate Issuer Solutions
P.O. Box 1342
Brentwood, NY 11717
www.broadridge.com

Investor Information

Exchange: Nasdaq Global Select Market
Ticker Symbol: ACRS

Investor Relations

Stockholder inquiries should be directed to:

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Email: investors@aclaristx.com.

Legal Counsel

Cooley LLP
One Freedom Square
Reston Town Center
11951 Freedom Drive
Reston, VA 20190

Independent Auditors

PricewaterhouseCoopers LLP
Two Commerce Square
2001 Market Street | Suite 1800
Philadelphia, PA 19103

Forward-Looking Statements

This annual report to stockholders contains forward-looking information about Aclaris' future operating and financial performance, business plans and prospects, and product candidates that involves substantial risk and uncertainties. Please refer to the special note regarding forward-looking statements in this annual report for additional information regarding our forward-looking statements.



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