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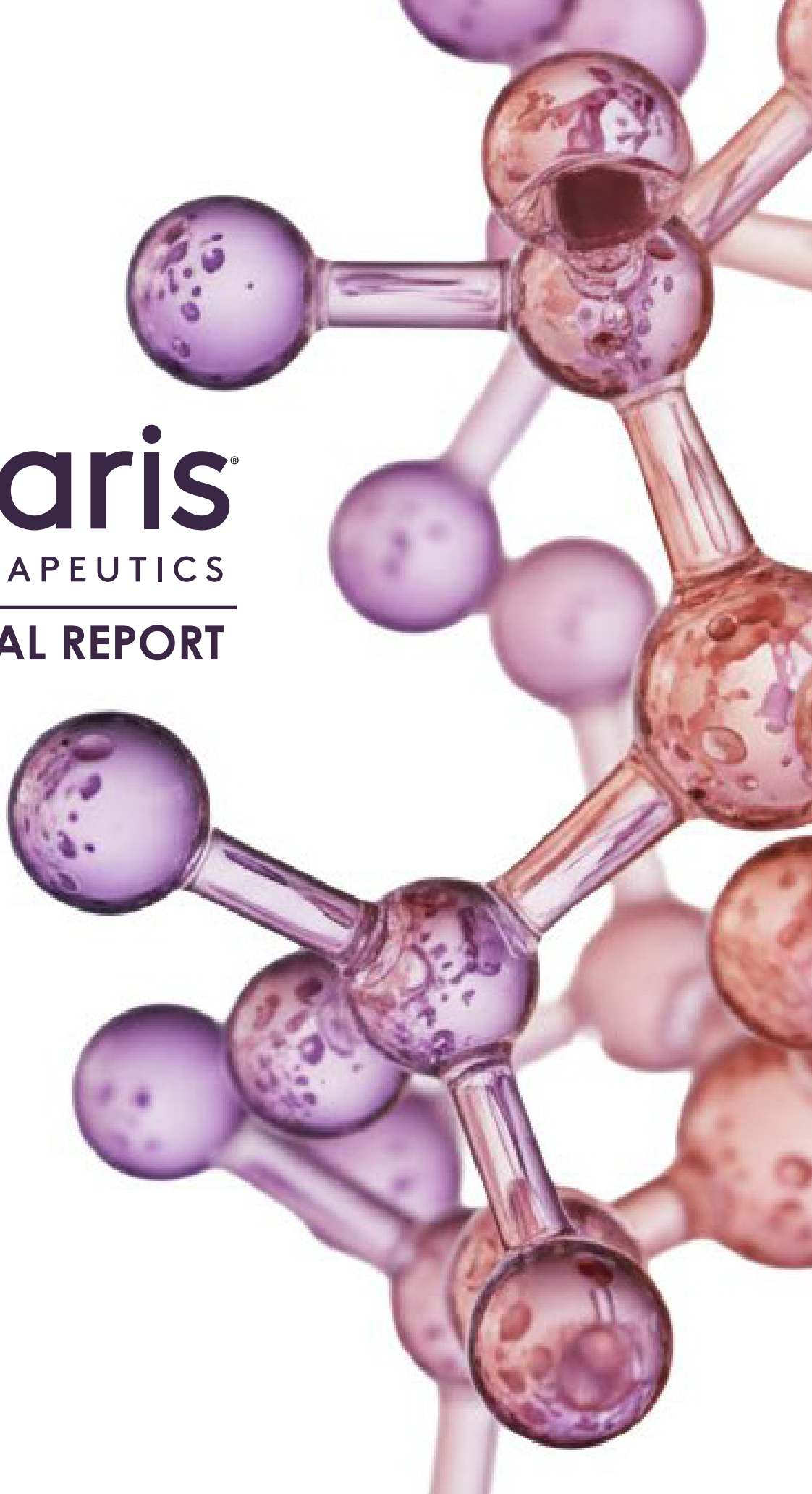
THERAPEUTICS

2025 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, 2025 **Commission file number 001-37581**

ACLARIS THERAPEUTICS, INC.

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

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 30, 2025, 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 $149.2 million based on the closing price of the registrant's common stock, as reported by the Nasdaq Global Select Market, on such date.

As of January 30, 2026, 120,595,189 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 timing of our planned clinical trials of our product candidates and the reporting of the results from these trials;
- the clinical utility of our product candidates and our expectations about their properties and therapeutic effects;
- our plans and expectations related to manufacturing capabilities and strategy;
- our expectations regarding coverage and reimbursement of our product candidates, if approved;
- the timing of our regulatory filings and approvals for our product candidates;
- our intellectual property position;
- our plans to identify and consummate 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;
- the size and growth potential of the markets for our product candidates;
- 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 RHOFADE, are the property of their respective owners. Unless the context requires otherwise, references in this report to "Aclaris," the "Company," "we," "us," and "our" refer to Aclaris Therapeutics, Inc. and its subsidiaries.

TABLE OF CONTENTS

PART I

Item 1. Business

Overview

We are a clinical-stage biopharmaceutical company focused on discovering and developing novel small and large molecule product candidates for immuno-inflammatory diseases. Our proprietary KINect drug discovery platform coupled with our integrated discovery approach to small and large molecules enables us to identify and advance product candidates designed to have superior target affinity, specificity and potency. We are seeking to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our novel product candidates.

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 achieving this goal includes the following key elements:

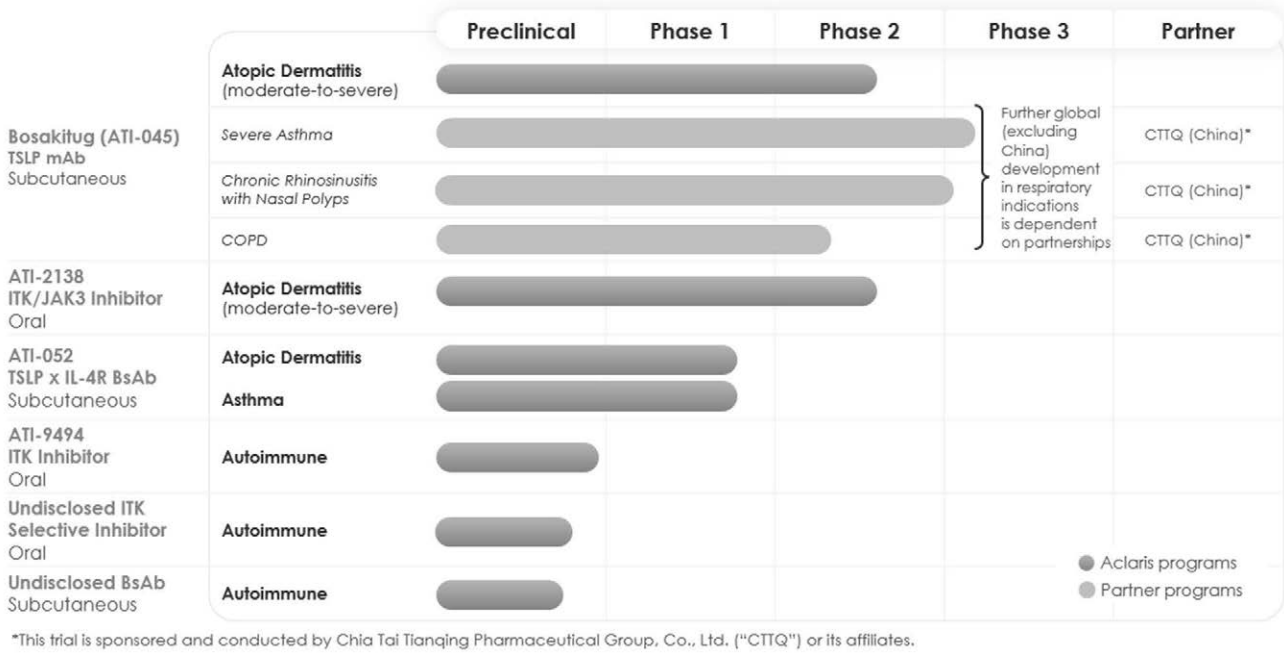
- **Leverage discovery, research and development expertise.** We have state-of-the-art capabilities and expertise in small molecule and antibody development, including cell and molecular biology, biochemistry, enzymology, biomarker development, immunology, translational research, in vivo efficacy models, structure-based drug design ("SBDD"), and bioanalytical, computational, and medicinal chemistry. In addition, our team of scientists and professionals has broad experience in clinical development and strategy across atopic, respiratory, inflammatory and immunologic diseases.
- **Develop innovative biologic product candidates targeting validated pathways.** We are advancing biologics programs comprising monoclonal and multispecific antibodies targeting 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 and bispecific 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 low dissociation rate, long residence time and high potency. TSLP, a master regulator of type 2 ("Th2") immune responses, is a broadly active 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 ("IL-4Rα"), which blocks signaling of both IL-4 and IL-13, potentially offering enhanced efficacy through dual pathway inhibition. By pursuing both traditional monoclonal antibodies and innovative multispecific approaches, we aim to develop differentiated biological therapies that address significant unmet needs in immuno-inflammatory diseases.
- **Create small molecule medicines through kinome innovation utilizing our proprietary KINect platform.** We are exploring the kinome, a subset of the human genome and one of the largest of all human gene families, responsible for signal transduction controlling cellular responses. 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 including autoimmune, cardiovascular, inflammatory, and metabolic disorders, 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 2025, the kinase inhibitors market was valued at over $67 billion and is expected to grow to over $94 billion by 2030. 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. The KINect platform is designed with the goal of expanding the druggable kinome, solving class challenges including affinity and selectivity, and providing a faster path to high quality inhibitor assets. We are focused on novel approaches toward the design and development of kinase inhibitors that target key enzymes involved in chronic inflammation and autoimmune disease. For example, we are developing a portfolio of highly potent, oral small molecule covalent inhibitors of IL-2-inducible tyrosine kinase ("ITK"). These include ATI-2138, an ITK and Janus

kinase ("JAK") 3 dual inhibitor, and JAK-sparing ITK inhibitors, including ATI-9494.

- **Broaden our drug development pipeline internally and externally.** A key element of our strategy is to build and expand our pipeline of product candidates. We may seek to in-license or acquire additional product candidates, in addition to developing assets in-house.
- **Identify and consummate transactions with third-party partners for our product candidates.** We intend to identify and consummate 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.



*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, blocking its interaction with the receptor complex and disrupting signal transduction. This mechanism prevents immune cells targeted by TSLP from releasing proinflammatory cytokines. Bosakitug has potential best-in-class properties, including a very high affinity to TSLP, very high potency, an extremely low dissociation rate from TSLP leading to long residence time and enhanced neutralization activity, and a half-life that can potentially support an extended dosing interval. The high affinity and low dissociation observed with bosakitug may be the result of unique biparatopic binding to both the N- and C-terminus of TSLP. Bosakitug has the potential to treat a variety of atopic, immunologic and respiratory diseases. We exclusively license global rights (excluding Mainland China, Macau, Hong Kong and Taiwan ("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, 94% of patients receiving bosakitug achieved at least a 75% improvement in the Eczema Area and Severity Index ("EASI"), 65% of patients achieved EASI-90, and 88% of patients achieved an Investigator's Global Assessment ("IGA") score of 0 or 1 (clear or almost clear skin), at week 26 (n=17). Bosakitug demonstrated a strong pharmacodynamic profile and 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.

In June 2025, we initiated a Phase 2 trial to investigate the efficacy, safety, tolerability, pharmacokinetics ("PK") and pharmacodynamics ("PD") of bosakitug compared to placebo in approximately 96 patients with moderate to severe

atopic dermatitis. The primary endpoint is percent change from baseline in EASI at week 24. Secondary endpoints at week 24 include EASI response (EASI-50, EASI-75, EASI-90), validated IGA response, body surface area ("BSA") response, and Peak Pruritus Numerical Rating Scale ("PP-NRS") score, relative to baseline. We expect to announce top-line data in the second half of 2026. Bosakitug is also currently being studied in severe asthma, chronic rhinosinusitis with nasal polyps and moderate to severe chronic obstructive pulmonary disease in China by CTTQ. CTTQ licenses bosakitug from Biosion in Greater China. Our clinical focus for bosakitug will remain on dermatological immuno-inflammatory indications and further global (excluding Greater China) development in respiratory indications will be dependent on entering into potential partnerships.

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

ATI-2138 is a highly potent and selective novel investigational dual inhibitor of ITK and JAK3 for the potential treatment of T cell-mediated autoimmune diseases. The unique dual pharmacology of ATI-2138 regulates T cell development and function both upstream (ITK) and downstream (JAK3), which may provide a more potent and complete anti-inflammatory response.

In July 2025, we announced positive top-line results from our open-label, single-arm Phase 2a trial of ATI-2138 in patients with moderate to severe atopic dermatitis. The trial met the primary and key secondary endpoints. The trial was designed to investigate the safety, tolerability, PK, efficacy, and PD of 10 mg of ATI-2138 administered twice daily ("BID") for 12 weeks. The trial enrolled 14 patients in the United States, with 12 patients completing treatment and up to 10 patients available for the per protocol analysis. The primary endpoints were safety related parameters and the secondary endpoints included PD and efficacy related measures. No meaningful safety findings were observed, and ATI-2138 was very well tolerated. We observed consistent and rapid improvement across the efficacy assessments, with a mean and median improvement in EASI score at week 12 of 61% and 77%, respectively. Excluding one patient determined to be a statistical molecular outlier by more than four standard deviations who demonstrated systemic findings inconsistent with atopic dermatitis alone including significant non-lesional inflammation and who was not fully compliant with study drug administration, the mean and median improvement in EASI score at week 12 was 77% and 82%, respectively. At week 12, 63% of patients experienced a greater than or equal to 4-point improvement (which is considered a clinically meaningful response) in PP-NRS. Additional clinical results presented at the European Academy of Dermatology and Venerology conference in September 2025 further clarified the rapid improvements across efficacy measures, including week 4 decreases of 64% in BSA response ($p<0.001$), 77% in EASI score ($p<0.001$), and 45% in PP-NRS ($p<0.01$). These results were sustained through end of treatment at week 12. ATI-2138 demonstrated near complete and sustained inhibition and occupancy of ITK ranging from approximately 90% at peak to 60% to 70% at trough, and a high level of inhibition of JAK3. Proteome and transcriptome lesional skin tap strip analyses showed significant ATI-2138-dependent reduction of multiple inflammatory pathways associated with ITK, including strong downregulation of Th2, Th17, and T cell receptor ("TCR") pathways, along with the Th1 pathway and fibrosis-related markers. The decreases in inflammatory and fibrosis-related markers positively and strongly correlated with improvements in clinical scores.

We are exploring the potential of ATI-2138 in additional indications that are relevant to the dual pharmacology and mechanism of action, including certain alopecias and other inflammatory disorders.

ATI-052, an Investigational, Novel Anti-TSLP and Anti-IL-4Rα Bispecific Antibody

ATI-052 is an investigational, novel, humanized anti-TSLP and anti-IL-4Rα bispecific antibody that exhibits high binding affinity to and dual blockage of both the upstream TSLP receptor signal transduction and downstream IL-4Rα activation thereby inhibiting this central proinflammatory pathway. ATI-052 binds TSLP, which sits at the top of the inflammatory cascade; by targeting IL-4Rα, it blocks downstream signaling of both IL-4 and IL-13, two anti-inflammatory cytokines, which are critical components of Th2-mediated immunity and play a crucial role in the pathogenesis of inflammation and allergic diseases. ATI-052 utilizes the same TSLP antigen-binding fragment ("Fab") as bosakitug but is engineered to bind more tightly to the neonatal Fc receptor ("FcRn"), potentially extending its half-life. In addition, the AQQ mutation in the Fc limits effector functionality, reducing off-target binding and potential toxicity. ATI-052 has the potential to treat a variety of atopic, immunologic and respiratory diseases. We exclusively license global rights (excluding Greater China) to ATI-052 from Biosion.

In January 2026, we announced positive interim results from our Phase 1a single ascending dose ("SAD") and multiple ascending dose ("MAD") portion of our first-in-human study evaluating ATI-052 in healthy volunteers. The

randomized, blinded, placebo-controlled study enrolled 48 participants across four SAD cohorts (receiving single doses of 30, 120, 360, or 720 mg or placebo) and two MAD cohorts (receiving five doses of 240 or 480 mg or placebo administered every seven days). ATI-052 demonstrated a favorable safety and tolerability profile across all dose levels, with treatment-emergent adverse events ("TEAEs") being predominantly Grade 1 in severity. The most common TEAE was mild, self-resolving injection site redness, and notably, no conjunctivitis was observed in any cohort. No Grade 3 TEAEs related to study drug, serious adverse events, or discontinuations due to adverse events occurred. The PK profile showed dose proportionality across the pharmacologic dose range with an effective half-life of at least 26 days. PD results demonstrated robust target engagement with concentration-dependent inhibition of IL-4 and TSLP stimulated CCL17/TARC at all doses tested. At 360 mg, ATI-052 achieved complete and sustained inhibition through week three, with near complete inhibition of TSLP stimulated CCL17/TARC observed at least six weeks after administration. These combined PK and PD characteristics support the potential for dosing intervals of up to every three months. We expect to announce complete top-line results from the SAD and MAD cohorts in the second quarter of 2026.

Based on these positive results, we initiated a Phase 1b proof-of-concept trial in atopic dermatitis in January 2026 and a Phase 1b proof-of-concept trial in asthma in February 2026, with top-line data from both studies expected in the second half of 2026. We plan to initiate a Phase 2b program for ATI-052 with asthma and atopic dermatitis as potential first indications, in the second half of 2026.

ATI-9494, an Investigational, Oral Covalent ITK Inhibitor, and Other JAK-Sparing ITK Inhibitors

We are developing ATI-9494, a highly potent, oral, covalent, investigational dual inhibitor of ITK and Resting Lymphocyte Kinase (TXK), and other covalent JAK-sparing ITK inhibitors with differentiated pharmacological properties and selectivity profiles. These inhibitors have the potential to differentially modulate T cell biology across a broad range of disease indications with extended half-lives and potential best-in-class potency, ITK occupancy, and ITK activation at low doses. We expect to file an IND application for ATI-9494 in the second half of 2026.

Discovery and Preclinical Programs

We conduct small molecule drug discovery through KINect, our proprietary drug discovery platform. We also engage in discovery efforts for novel, injectable, multi-specific antibodies. Through our integrated discovery approach, we can progress product candidates from concept through lead optimization, employing robust screening cascades and protein characterization techniques to identify molecules with desired therapeutic properties.

Our KINect platform allows us to address challenges associated with difficult to drug kinases including selectivity and biochemical efficiency, 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 approach involves the following mechanisms: (1) reversible and irreversible covalent inhibitors, (2) molecular glue/complex targeted inhibitors, (3) tissue specific inhibitors, and (4) targeted protein degraders. These novel approaches are currently being utilized to prosecute additional validated, difficult to drug kinase targets with the goal of demonstrating broad target utility. Our small molecule discovery efforts center on targeting kinases that play pivotal roles in various inflammatory and autoimmune pathways.

Reversible and Irreversible Covalent Inhibitors (small molecules inhibiting kinases by forming irreversible bonds with a cysteine at the active site): 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 (small molecules that stabilize kinases in an inactive confirmation or ready them for degradation): 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.

Tissue Specific Inhibitors (small molecules that inhibit kinases in target tissues with minimal systemic exposure): Target-specific inhibitors are drugs, often small molecules, designed to block specific proteins (like kinases) or pathways driving diseases including immunologic and inflammatory disorders. We believe that such inhibitors provide a unique opportunity to target certain diseases with highly specific compounds which may allow us to overcome potential systemic safety concerns and raise the efficacy ceiling.

Targeted Protein Degraders (small molecules that trigger the degradation of specific proteins by the ubiquitin/proteasome pathway): 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.

Our discovery efforts to develop multi-specific antibodies are focused on generating antibodies with superior target affinity, specificity, and potency utilizing combinations of (a) two or more clinically validated targets with non-overlapping biology, (b) clinically validated targets with novel biology, and/or (c) synergistic target combinations in an effort to address shortcomings of single drug administration. This complementary approach to our small molecule programs enables us to pursue optimal therapeutic modalities for each target and indication of interest. For example, we are progressing several bispecific antibodies utilizing the bosakitug anti-TSLP binding region paired with binding fragments targeting other undisclosed cytokine signaling pathways.

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

Other Investigational Product Candidates

Lepzacitinib, an Investigational Topical "Soft" JAK 1/3 Inhibitor

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

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, AMG-104), KeyMed Biosciences (CM326), Uniquity Bio (solrikitug), Windward Bio and Harbour BioMed and Kelun-Biotech (WIN378/HBM9378), GlaxoSmithKline ("GSK") (GSK5784283), Generate Biomedicines (GB-0895), Qyuns

Therapeutics (QX008N), and UpStream Bio (verekutig).

With respect to ATI-052, our primary competitors include those developing multi-specific antibodies designed to inhibit both TSLP and IL-4Rα activity, such as Innovent Biologics (IBI3002) and Pfizer (PF-07275315).

Competitors for ATI-052 may also include those developing or commercializing multi-specific antibodies targeting two or more of TSLP, IL-4, and IL-13. For example, we are aware of Regeneron Pharmaceuticals and Sanofi (dupilumab), Sanofi (lunsekimig), Pfizer (PF-07264660), and KeyMed Biosciences (CM512).

With respect to bosakitug and ATI-052 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, tralokinumab), Pfizer (crisaborole; abrocitinib), Eli Lilly (lebrikizumab), Dermavant Sciences (tapinarof), Galderma (nemolizumab), and Regeneron Pharmaceuticals and Sanofi (dupilumab). In addition, we are aware of a number of companies developing and conducting clinical trials for investigational product candidates that could compete with bosakitug and ATI-052 in each case if approved, for the treatment of atopic dermatitis. With respect to ATI-052 as a potential treatment for asthma, existing therapeutics for asthma include controller medications, reliever medications, as well as biologics from Genentech and Novartis (omalizumab), Sanofi and Regeneron (dupilumab), GSK (mepolizumab, depemokimab), Amgen and AstraZeneca (tezepelumab), and AstraZeneca (benralizumab), with other products in development.

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). In addition, 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 (baricitinib), AbbVie (upadacitinib), and Sun Pharmaceutical (deuruxolitinib).

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 an issued patent and pending applications in the United States, European Union, Japan and South Korea directed to TSLP monoclonal

antibodies, including bosakitug. Our issued U.S. patent expires in 2043 with its patent term adjustment, and the pending applications in the United States and foreign countries, 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 international patent application filed under the Patent Cooperation Treaty ("PCT") 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 ATI-9494, and methods of use that expire, or would expire, between 2035 and 2046, subject to any applicable patent term adjustment or extension that may be available in a particular country. For example, we own multiple 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 PCT application 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 expire in 2044, and to methods of using ATI-2138 for treating atopic dermatitis, which if issued, would expire in 2045, in each case subject to any applicable adjustment or extension. We also own provisional applications on novel JAK-sparing inhibitors of ITK, including ATI-9494, which if issued, would expire in 2046.

With respect to our bispecific antibody development program, we exclusively license pending applications in the United States, Europe and other foreign countries 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.

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 protection 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 Greater China. In connection with the Biosion Agreement, we also entered into a collaboration agreement (the "CTTQ Agreement", and together with the Biosion Agreement, the "Biosion Agreements") with Biosion and CTTQ, a licensee of bosakitug in Greater China.

Under the Biosion Agreements, we paid, in the aggregate, $30.0 million in upfront cash consideration, $4.5 million for the reimbursement of certain development costs, plus $6.2 million for the reimbursement of certain development costs and drug product material. 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) up to $125 million upon the achievement of specified regulatory milestones beginning 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, and (iv) 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 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, 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, among others, our investigational product candidates 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 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

Our current and future activities, as well as our potential third-party partners' activities, may, directly or indirectly, expose us and 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 any products for which marketing approval is obtained is sold, marketed and distributed. 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.

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, prohibit, 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 such laws.

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. 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 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, among other things, imposes standards relating to the privacy and security of individually identifiable health information on HIPAA covered entities, which include certain healthcare providers, healthcare clearing houses and health plans, and individuals and entities that provide services on their behalf that involve individually identifiable health information, known as business associates, as well as their covered subcontractors. 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 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.

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, among other things, 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. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA"), was signed into law, which narrowed access to Affordable Care Act marketplace exchange enrollment and declined to extend the Affordable Care Act enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired Affordable Care Act subsidies. We expect that additional United States federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the federal government will pay for healthcare products and services.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. For example, in August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions in Medicare payments to providers of 2% per fiscal year, which began in 2013 and will stay in effect through 2032 unless additional Congressional action is taken.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at the U.S. Department of Health and Human Services ("HHS"), the FDA, CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager

payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in *Loper Bright Enterprises v. Raimondo*, the United States Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our or our potential partners' operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

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. Any such importation plans, if implemented, may result in lower drug prices for products covered by those programs.

Existing and future federal and state health care reform measures 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 protection 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. Further, the containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. 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, 2025, we had 73 total employees, of which 69 were full-time employees. 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. In addition to our employees, we engage consultants and independent contractors to provide flexibility in support of our business execution and objectives.

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 identify and consummate 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 identify and consummate 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 $64.9 million and $132.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, we had an accumulated deficit of $967.8 million. We have financed our operations over the last several years primarily from sales of equity securities and non-dilutive financing.

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:

- seek to identify and 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 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, 2025, we had cash, cash equivalents and marketable securities of $151.4 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 studies 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, tariff policies, 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 or other non-dilutive financing. 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 subject to more complex regulatory requirements than small molecule drugs. 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 identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our product candidates, which could harm our business.

The rapid advancement of artificial intelligence and computational drug discovery technologies could make our KINect platform and discovery approaches less competitive or obsolete, and our failure to successfully adopt and integrate artificial intelligence technologies could put us at a competitive disadvantage.

The pharmaceutical and biotechnology industries are experiencing rapid transformation through artificial intelligence ("AI"), machine learning ("ML"), and computational approaches to drug discovery and development. Large pharmaceutical companies and well-funded biotechnology companies are making substantial investments in AI-driven drug discovery platforms that may:

- identify product candidates faster and more efficiently than our KINect platform;
- reduce the time and cost required to progress from target identification to clinical candidate;
- enable competitors to explore larger areas of chemical and biological space; or
- provide more accurate predictions of clinical outcomes, reducing development risk.

Our KINect drug discovery platform, while innovative, may become less competitive if we fail to successfully integrate advanced AI and ML capabilities. Specifically:

- our proprietary chemical library and SBDD approaches may be replicated or surpassed by AI-driven generative chemistry platforms;
- competitors using AI may identify superior kinase inhibitors targeting the same pathways we are pursuing;
- AI-enabled clinical trial design and patient selection may allow competitors to achieve proof-of-concept more rapidly and efficiently; and
- our internal expertise and resources for AI/ML integration are limited compared to larger competitors.

Furthermore, the use of AI in drug discovery and development raises new regulatory uncertainties. Regulatory agencies including the FDA are still developing frameworks for evaluating AI-generated data and AI-assisted drug development processes. If we utilize AI technologies, we may face uncertainty about what data and documentation regulators will require regarding AI-generated discoveries, potential challenges to the patentability of AI-discovered compounds or methods, questions about data integrity, bias, or validity of AI-generated predictions, and/or additional regulatory scrutiny or requirements that could delay our development timelines.

Our ability to remain competitive will depend on our capacity to adopt and integrate appropriate AI and computational technologies, which will require significant investment in technology infrastructure, data systems, and personnel with specialized expertise. If we are unable to successfully leverage these technologies, or if we make substantial investments in AI approaches that do not yield productive results, our competitive position and financial condition could be materially harmed.

Additionally, the potential use of AI by contract research organizations, clinical trial sites, or regulatory agencies could change the standards and expectations for drug development, requiring us to adapt our processes and potentially increasing our costs and development timelines.

If we are unable to successfully develop our product candidates and identify and consummate 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 identify and consummate 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 treatments; 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 identify and consummate 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 the identification and consummation of 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. 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 Phase 2a trial of ATI-2138 in patients with atopic dermatitis was 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 identify and consummate 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;
- early-stage clinical trial results may be subject to variability due to small sample size and may not be indicative of results from future clinical trials;
- 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;
- third parties conducting clinical trials using our product candidates may produce issues such as poor data integrity, safety concerns, protocol violations, or failure to meet endpoints in these third-party trials, which 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, result in increased regulatory scrutiny, or impact our ability to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize such product candidates;
- 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 identify and consummate 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 identify and consummate 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 identify and consummate 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. Recruiting and retaining patients for clinical trials has become increasingly difficult and expensive, which could delay or prevent completion of our trials. 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 identify and consummate 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 or other unfavorable safety findings may be identified during the nonclinical or clinical 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 identify and consummate 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, exhibit adverse toxicological findings in nonclinical studies 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 nonclinical or clinical 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 or exhibit toxicological profiles in animal models 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. Our nonclinical studies may yield results that are not predictive of future clinical results or that reveal safety concerns that preclude further development. 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 or unfavorable nonclinical safety findings 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 identify and consummate 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 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. For example, we recently announced interim Phase 1a data for ATI-052. 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. 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 identify and consummate 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 identify and consummate 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 or nonclinical studies for our product candidates outside the United States. The FDA, EMA or comparable foreign regulatory authorities may not accept data from such studies.

We have conducted and may in the future conduct clinical and nonclinical studies for our product candidates outside the United States. In addition, our partners may conduct clinical and nonclinical studies 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 data from clinical and nonclinical studies 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 and nonclinical studies 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 studies 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 studies 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 studies, 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 studies outside of the United States, or delay or adversely affect the timeliness of such studies. 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.

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.

See "Item 1. Business—Competition" above for additional information regarding the competition we face.

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 which receive commercial approval, 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. Further, the containment of healthcare costs also has become a priority of federal, state and foreign governments and the prices of drugs have been a focus in this effort. For example, HHS imposes rebates on many Medicare Part B and Medicare Part D products to penalize price increases that outpace inflation on an annual basis. HHS has also been empowered to negotiate the price of certain single-source drugs that have been on the market for at least seven (7) years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to twenty (20) products will be selected by HHS for the Medicare Drug Price Negotiation Program. Products subject to the Medicare Drug Price Negotiation Program are expected to experience a significant reduction in reimbursement from the Medicare program on a per unit basis. 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 identify and consummate 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 Biologics") for the production of product necessary to complete our upcoming clinical trial for bosakitug. We also rely on WuXi AppTec (HongKong) Limited ("WuXi AppTec", and together with WuXi Biologics, "WuXi") to conduct toxicology studies. The BIOSECURE Act, which prohibits, among other things, U.S. federal funding in connection with biotechnology equipment or services produced or provided by certain named Chinese "biotechnology companies of concern" ("BCCs") 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. While the enacted version of the BIOSECURE Act does not specifically name companies, it establishes a process for the Office of Management and Budget ("OMB") to publish a list of BCCs by December 18, 2026**.** Such BCCs will include entities on the U.S. Department of Defense's annual List of Chinese Military Companies ("1260H List") and also entities so designated by OMB through a separate designation process. Companies previously identified in legislative drafts, such as WuXi, remain at risk of being designated as BCCs through this process or by inclusion on the 1260H list. The Act includes a five-year grandfathering provision for existing commercial agreements executed prior to the implementation of the Federal Acquisition Regulation ("FAR") revisions, which are expected by mid-2028. The implementation of the BIOSECURE Act could materially impact our current and future agreements with WuXi or other Chinese manufacturers. If WuXi or our other partners are designated as BCCs, we

may be required to transition to alternative manufacturers and service providers to maintain eligibility for federal contracts, grants, or clinical trial reimbursements. Such a transition could be time-consuming, resource-intensive, and may require FDA supplemental approvals, potentially causing significant delays or impairments to our clinical development timelines and business operations.

Additionally, export controls or restrictions on the transfer of certain technologies, materials, or data could disrupt our collaborations, particularly our agreement with CTTQ in Greater China. Changes in the trade relations between the United States and China could:

- limit our ability to receive clinical data from CTTQ's ongoing trials in China;
- restrict data sharing under our license agreements;
- prevent us from accessing drug product manufactured in China for our clinical trials; or
- impact our collaboration agreements and milestone payments.

We may not be able to quickly identify alternative suppliers or manufacturers and any such transitions would require regulatory approval, validation studies, and significant time and expense. Any significant disruption in our supply chain or increase in costs due to tariffs or trade restrictions could delay our clinical programs, increase our operating expenses, and materially harm our business and financial condition.

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 identify and consummate 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 identify and consummate 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 identify and consummate 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 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 identify and consummate transactions 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 issued U.S. patent covering bosakitug and methods of use expires in 2043 and our pending U.S. application covering ATI-052, if issued, would also expire in 2043. Our issued U.S. patents directed to ATI-2138 and methods of use expire in 2039. We are pursuing additional patent protection for our product candidates, such as additional 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 issued patents and pending applications in the United States, Europe, Japan and South Korea for our TSLP monoclonal antibodies, including bosakitug. We have issued U.S. patents directed to ATI-2138, and pending applications in foreign markets directed to ATI-2138. We currently have pending applications in the United States, Europe, Japan, South Korea and other major markets directed to ATI-052 and other TSLP and IL-4R bispecific antibodies.

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 identify and consummate 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 identify and consummate 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 identify and consummate 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 identify and consummate 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 issued U.S. patent covering bosakitug expires in 2043. 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. 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 and our potential third-party partners' operations may subject us and such partners, directly or indirectly, to broadly 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 profitability.

Our and our potential third-party partners' activities may expose us and them, directly or indirectly, 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 any product candidates for which marketing approval is obtained is sold, marketed and distributed. 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;
- 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.

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 July 4, 2025, the OBBBA was signed into law, which narrowed access to Affordable Care Act marketplace exchange enrollment and declined to extend the Affordable Care Act enhanced advanced premium tax credits that expired at the end of 2025, which, among other provisions in the law, are anticipated to reduce the number of Americans with health insurance. The OBBBA also is expected to reduce Medicaid spending and enrollment by implementing work requirements for some beneficiaries, capping state-directed payments, reducing federal funding, and limiting provider taxes used to fund the program. Congress is considering proposed legislation intended to further reduce healthcare costs with alternatives to replace the expired Affordable Care Act subsidies. We expect that additional U.S. federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that the U.S. federal government will pay for healthcare products and services, which could result in reduced demand for our product candidates that receive marketing approval or additional pricing pressures. 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 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 Bipartisan Budget Act of 2018 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 that receive marketing approval.

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.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, CMS and related agencies. These actions, presently directed by executive orders or

memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. For example, the current administration has announced agreements with several pharmaceutical companies that require the drug manufacturers to offer, through a direct-to-consumer platform, U.S. patients and Medicaid programs prescription drug Most-Favored Nation pricing equal to or lower than those paid in other developed nations, with additional mandates for direct-to-patient discounts and repatriation of foreign revenues. Other recent actions, for example, include (1) directing agencies to reduce agency workforce and cut programs; (2) directing HHS and other agencies to lower prescription drug costs through a variety of initiatives, including by improving upon the Medicare Drug Price Negotiation Program and establishing Most-Favored-Nation pricing for pharmaceutical products; (3) imposing tariffs on imported pharmaceutical products; and (4) as part of the Make America Healthy Again Commission's Strategy Report released in September 2025, working across government agencies to increase enforcement on direct-to-consumer pharmaceutical advertising. Additionally, the current administration recently called on Congress to enact "The Great Healthcare Plan," to codify and expand Most-Favored Nation pricing, lower government subsidies to private insurance companies, increase healthcare price transparency, expand pharmaceutical drugs available for over-the-counter purchase, and enact restrictions on pharmacy benefit manager payment methodologies, among other things. These actions and policies may significantly reduce U.S. drug prices, potentially impacting manufacturers' global pricing strategies and profitability, while increasing their operational costs and compliance risks. In June 2024, in *Loper Bright Enterprises v. Raimondo*, the United States Supreme Court greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our or our potential partners' operations. Congress may introduce and ultimately pass health care related legislation that could impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

Individual states in the United States have also 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. Legally mandated price controls on payment amounts by third-party payors or other restrictions could materially and adversely affect our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for our product candidates or put pressure on our product pricing.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or judicial action in the United States or any other jurisdiction. If we or any of our potential partners are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, we may not achieve or sustain profitability.

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 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, data about our personnel, data about 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 ("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 with whom we work.

In addition to "comprehensive" state privacy laws like CCPA, we are currently or may become in the future subject to 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 activist 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. Additionally, the U.S. Department of Justice issued a rule entitled the "Preventing Access to U.S. Sensitive Personal Data and Government-Related Data by Countries of Concern or Covered Persons," which places additional restriction on certain data transactions involving countries of concern (*e.g.*, China, Iran, Russia) and covered persons (i.e., individuals and entities who are designated as such by the U.S. Attorney General or considered "foreign persons" and are majority owned by, organized under the laws of, a primary resident in, or a contractor of, a covered person or country of concern, as applicable) that may impact certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals and investor agreements. The rule also applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours and may impact our ability to engage in transactions or agreements with certain third parties in the future. Violations of the rule could lead to significant civil and criminal fines

and penalties. If notwithstanding our efforts to comply with these laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

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 such 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 with whom we work may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties with whom we work 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 or restrictions on processing personal data; orders to destroy or not use personal data; and imprisonment of company officials. 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. Jesse Hall, our Chief Medical Officer, Roland Kolbeck, Ph.D., 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, 2025, we had federal and state net operating loss ("NOL") carryforwards of $568.2 million and $100.7 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, 2025, we also had federal research and development tax credit carryforwards of $2.5 million which will begin to expire in 2045. 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 (the "Code"), and corresponding provisions of state law, if a corporation undergoes an "ownership change," which is generally defined as a greater than 50% change, by value, in its equity ownership over a three-year period, the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change income may be limited. We completed an analysis under Section 382 for NOLs generated through December 31, 2024, and concluded that an ownership change occurred as of December 30, 2024. As a result of this ownership change, a component of our research and development tax credits and state NOL carryforwards will expire prior to utilization. Accordingly, we have recorded an adjustment to write down our research and development tax credits and state NOL deferred tax assets in the amount of $21.9 million and $19.0 million, respectively. The write down of these deferred tax assets resulted in a corresponding adjustment to our valuation allowance. 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 or data, or those of the third parties with whom we work, 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. We and the third parties with whom we work 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 with whom we work. Such threats are prevalent and continue to increase, 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 with whom we work 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 with whom we work are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deepfakes, 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 attacks, 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. For example, we rely on our third-party research collaborators for research and development of our product candidates and other third parties to conduct clinical trials, and security incidents or other similar events relating to their information technology systems could seriously harm our business. 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, threat actors may use an initial compromise of one part of our environment to gain access to other parts of our environment, or leverage a compromise of our networks or systems to gain access to the networks or systems of third parties with whom we work, such as through phishing or supply chain attacks.

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 with whom we work. For example, we have been the target of unsuccessful phishing attempts in the past, and expect such attempts will continue in the future. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to operate our business. For example, the loss of clinical trial data from completed, ongoing or future clinical trials could result in delays in or denials of our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

We may expend significant resources or modify our business activities (including our clinical trial activities) to try to protect against security incidents. Additionally, certain data privacy and security obligations have 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 with whom we work) 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 material 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. For example, to the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential or proprietary or personal information, we could incur liability, our competitive position could be harmed, and the further development and commercialization of our product candidates could be delayed, result in substantial costs, diversion of management attention, and other adverse consequences.

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 macroeconomic conditions, including tariff policies and inflationary pressure, as well as constrained capital markets, could limit our ability to grow our business, raise capital 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.

Our industry is sensitive to global and domestic economic conditions and capital market dynamics. In 2025, the biotechnology industry faced significant macroeconomic headwinds, including trade policy uncertainty driven by tariff volatility, which created substantial uncertainty affecting pharmaceutical supply chains, active pharmaceutical ingredient sourcing, and overall investor sentiment toward the life sciences sector. Although pharmaceutical products have historically been exempt from certain tariffs, the ongoing Section 232 investigations and potential tariffs on pharmaceutical imports could increase our operating costs, disrupt our supply chain relationships, or force us to reconfigure our manufacturing and sourcing strategies.

The biotechnology capital markets may also be impacted by U.S. regulatory uncertainty amid agency leadership changes and shifting policy priorities. As a company without approved products generating revenue, we may be particularly vulnerable to these capital market conditions. Higher interest rates have increased the cost of capital and have generally made investors more selective, favoring companies with later-stage assets and established commercial operations. Continued volatility or deterioration in equity markets, prolonged elevated interest rates, or further trade policy disruptions could materially impair our ability to raise additional capital on acceptable terms, if at all. This could force us to delay, reduce, or eliminate research and development programs, or delay or modify clinical trial designs.

Additionally, macroeconomic uncertainty could affect our collaborators, suppliers, and potential partners, potentially leading to delayed payments, reduced collaboration funding, or renegotiation of existing agreements. Government shutdowns or prolonged budget disputes may also delay FDA regulatory reviews, CMS rulemaking, or other agency actions critical to our product development timelines. The combination of trade policy uncertainty, capital market constraints, and regulatory unpredictability makes it difficult to accurately forecast and plan future business activities, and any of these factors could materially and adversely affect our business, financial condition, results of operations, and prospects.

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 400,000,000 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. The OBBBA, the Inflation Reduction Act enacted in 2022, the Coronavirus Aid, Relief, and Economic Security Act enacted in 2020, and the Tax Cuts and Jobs Act enacted in 2017 made many significant changes to the Code. Future guidance from the Internal Revenue Service and other tax authorities with respect to any legislation may affect us, and certain aspects of such legislation could be repealed or modified in future legislation or sunset in future years. 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, and may subject us to evolving regulatory requirements.

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 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.

A growing number of jurisdictions and regulators are adopting laws and regulations, as well as focusing enforcement efforts, related to artificial intelligence. The use of such technologies in compliance with ethical standards and societal expectations is also subject to increasing scrutiny. These developments may increase our compliance burden and costs in connection with use of artificial intelligence and lead to legal liability if we fail to meet evolving legal standards or if use of such technologies results in harms or other causes of action we did not predict. For example, the European Union's Artificial Intelligence Act ("AI Act") entered into force on August 1, 2024, with most provisions becoming effective on August 2, 2026. This legislation imposes significant obligations on providers and deployers of artificial intelligence systems, and encourages providers and deployers of artificial intelligence systems to account for EU ethical principles in their development and use of these systems. The scope of requirements depends on legal and risk determinations that rely on novel legal provisions that have not yet been interpreted by courts or regulators, and non-compliance can lead to significant fines.

Likewise, recent state legislative developments in the United States have introduced emerging compliance risks for companies that develop or deploy AI technologies, which may impose novel requirements on AI developers and users. These state-level initiatives reflect a growing trend toward AI regulation in the absence of federal legislation. As a result,

we may face a fragmented and evolving compliance landscape that could increase operational complexity, regulatory scrutiny, and legal exposure associated with the use or development of AI technologies. In addition, various federal regulators have issued guidance and focused enforcement efforts on the use of AI in regulated sectors. The FDA, for example, issued guidance on the use of AI in medical devices, requiring detailed risk management and review processes to obtain approvals. If we develop or use AI systems governed by these laws or regulations, we will need to meet higher standards of data quality, transparency, monitoring and human oversight, and we would need to adhere to specific and potentially burdensome and costly ethical, accountability, and administrative requirements, with the potential for significant enforcement or litigation in the event of any perceived non-compliance.

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, contract research organizations, application providers, supply chain resources, 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, analyzing reports of threats and threat actors, conducting scans of the threat environment, conducting vulnerability assessments, conducting audits, and conducting threat assessments for internal and external threats. We also engage third parties to conduct annual penetration tests and tabletop incident response exercises, 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; systems monitoring; employee security training; penetration testing; cyber insurance; and, as appropriate, inclusion of cybersecurity requirements in our contracts.

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 consultants, cybersecurity software providers, managed cybersecurity service providers, 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 or data, or those of the third parties with whom we work, 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 IT, 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 office space for our headquarters in Wayne, Pennsylvania, under a lease agreement which has a term through February 2029.

We also sublease 20,433 square feet of office and laboratory space in St. Louis, Missouri, under a sublease agreement which 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 proceedings 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 30, 2026, we had 120,595,189 shares of common stock outstanding held by 46 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 discovering and developing novel small and large molecule product candidates for immuno-inflammatory diseases. Our proprietary KINect drug discovery platform coupled with our integrated discovery approach to small and large molecules enables us to identify and advance product candidates designed to have superior target affinity, specificity and potency. We are seeking to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize our novel product candidates. In addition, we 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 $64.9 million for the year ended December 31, 2025 and $132.1 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $967.8 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 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 non-dilutive financing. 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, tariff policies, 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", and together with the Biosion Agreement, the "Biosion Agreements") 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 Agreements, we, in the aggregate, (i) paid $30.0 million in upfront cash consideration, plus $4.5 million for the reimbursement of certain development costs, (ii) issued warrants (the "Warrants") to purchase 14,281,985 shares of our common stock and (iii) paid $6.2 million for the reimbursement of certain development costs and drug product material. We made cash payments of $6.2 million and $34.5 million as set forth in the Biosion Agreements during the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, 3,000,000 Warrants remained unexercised.

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.

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 payments 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 $3.8 million and $1.9 million of non-cash royalty income during the years ended December 31, 2025 and 2024, respectively.

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 upfront, regulatory and commercial milestone 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 may seek to monetize this asset.

We recognized $1.2 million and $3.0 million of licensing revenue during the years ended December 31, 2025 and 2024, respectively, a portion of which was payable to third parties.

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 (as defined below) 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 upfront, anniversary, regulatory and commercial milestone payments. In addition, Lilly has agreed to pay us other commercial milestone payments upon the achievement of specified milestones and additional anniversary payments as set forth in the agreement, as well as 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 $4.8 million of licensing revenue during the year ended December 31, 2025, all of which was payable to third parties. We recognized $13.2 million of licensing revenue during the year ended December 31, 2024, a portion of which was payable to third parties.

Asset Purchase Agreement with EPI Health, LLC

In October 2019, we sold RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE"), 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 RHOFADE 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 had been fully reserved. In September 2025, we sold all of our right, title and interest in our bankruptcy claims against EPI Health and wrote off the remaining reserved balance as it was deemed uncollectible.

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 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 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.

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. During the year ended December 31, 2025, we made cash severance payments

of $0.2 million to impacted employees. During the year ended December 31, 2024, we recognized severance expense of $2.7 million and made cash severance payments of $5.6 million to impacted employees.

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 treatment and 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, as described below.

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.

Other Income

Interest Income

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

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.

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 judgment 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 and comprehensive loss. 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 (collectively referred to as "probability of success"), which are based on an asset's current stage of development and a review of existing clinical data. Probability of success assumptions ranged between 21% and 40% at December 31, 2025. 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. As of December 31, 2025, the discount rate ranged between 6.7% and 8.7% depending on the year of each potential payment.

During the year ended December 31, 2025, we adjusted the probability of success for certain product candidates. This change and the passage of time resulted in an overall increase of $2.3 million in contingent consideration liability during the year ended December 31, 2025.

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. For service-based awards, we recognize stock-based compensation expense on a straight-line basis over the 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 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, 2025 and 2024

(In thousands)	Year Ended December 31, 2025	2024	Change
Revenues:			
Contract research	$ 1,872	$ 2,541	$ (669)
Licensing	5,954	16,179	(10,225)
Total revenue	7,826	18,720	(10,894)
Costs and expenses:			
Cost of revenue	2,091	2,792	(701)
Research and development	52,645	33,586	19,059
General and administrative	21,972	22,203	(231)
Licensing	5,193	12,666	(7,473)
Revaluation of contingent consideration	2,300	2,500	(200)
In-process research and development	—	86,905	(86,905)
Total costs and expenses	84,201	160,652	(76,451)
Loss from operations	(76,375)	(141,932)	65,557
Other income:			
Interest income	7,637	7,953	(316)
Non-cash royalty income	3,815	1,914	1,901
Total other income	11,452	9,867	1,585
Net loss	$ (64,923)	$ (132,065)	$ 67,142

Revenue

Contract Research

The decrease in contract research revenue for the year ended December 31, 2025 compared to the year ended December 31, 2024 was due to lower overall hours billed for laboratory services.

Licensing

The decrease in licensing revenue during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to larger milestone payments achieved under the license agreements with Sun Pharma and Lilly during the year ended December 31, 2024.

Cost and Expenses

Cost of Revenue

The decrease in cost of revenue during the year ended December 31, 2025 compared to the year ended December 31, 2024 was due to lower overall hours billed for laboratory services.

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, 2025	2024	Change
Bosakitug	$ 13,845	$ 299	$ 13,546
ATI-052	7,074	1,895	5,179
ATI-2138	4,921	4,209	712
ATI-9494	5,371	2,360	3,011
Discovery	3,872	3,415	457
Other research and development	1,488	6,827	(5,339)
Personnel	11,816	11,446	370
Stock-based compensation	4,258	3,135	1,123
Total research and development expenses	$ 52,645	$ 33,586	$ 19,059

Bosakitug

The increase in expenses for bosakitug during the year ended December 31, 2025 compared to the year ended December 31, 2024 was due to the timing of the acquisition of the in-licensed asset, which occurred in November 2024. The expenses consist primarily of product candidate manufacturing costs and clinical development expenses associated with a Phase 2 trial in atopic dermatitis.

ATI-052

The increase in expenses for ATI-052 during the year ended December 31, 2025 compared to the year ended December 31, 2024 was due to the timing of the acquisition of the in-licensed asset, which occurred in November 2024. The increase primarily consisted of preclinical development activities and clinical development expenses associated with a Phase 1a/1b program, partially offset by a decrease in product manufacturing costs.

ATI-2138

The increase in expenses for ATI-2138 during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to an increase in clinical development expenses associated with a Phase 2a trial in atopic dermatitis.

ATI-9494

The increase in expenses for ATI-9494 for the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to an increase in product candidate manufacturing costs, preclinical development activities, and IND-enabling studies.

Discovery

Discovery expenses consisted primarily of continued investment in our other JAK-sparing ITK inhibitors as we progress toward candidate selection.

Other research and development

The decrease in other research and development expenses during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to clinical development expenses associated with former development assets.

Personnel and stock-based compensation

The increase in personnel expenses during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to higher headcount. The increase in stock-based compensation expense during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to higher forfeiture credits during the year ended December 31, 2024.

General and Administrative

The following table summarizes our general and administrative expenses:

(In thousands)	Year Ended December 31, 2025	2024	Change
Personnel	$ 7,581	$ 6,786	$ 795
Professional and legal fees	3,757	4,508	(751)
Facility and support services	2,493	2,234	259
Other general and administrative	803	1,892	(1,089)
Stock-based compensation	7,338	6,783	555
Total general and administrative expenses	$ 21,972	$ 22,203	$ (231)

Personnel and stock-based compensation

The increase in personnel expenses during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to higher headcount. The increase in stock-based compensation expense during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to higher forfeiture credits during the year ended December 31, 2024.

Professional and legal fees

The decrease in professional and legal fees during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to legal, accounting, and other professional expenses incurred in 2024 in connection with acquisition and license agreements, partially offset by an increase in investor relations costs incurred in 2025.

Other general and administrative

The decrease in other general and administrative expenses during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to the sale of our bankruptcy claims against EPI Health and a decrease in insurance costs in 2025.

Licensing

The decrease in licensing expenses during the year ended December 31, 2025 compared to the year ended December 31, 2024 was primarily due to larger milestone payments achieved under the license agreements with Sun Pharma and Lilly during the year ended December 31, 2024, a portion of which was payable to third parties.

Revaluation of Contingent Consideration

The revaluation of contingent consideration loss decreased during the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily due to changes in estimated sales levels for certain product candidates during the year ended December 31, 2024.

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.

Non-cash Royalty Income

Non-cash royalty income includes income related to the proceeds from the sale of a portion of our OLUMIANT royalty payments to OMERS in July 2024.

Liquidity and Capital Resources

Overview

Since our inception, we have incurred net losses and negative cash flows from our operations. We have financed our operations over the last several years primarily through sales of our equity securities and non-dilutive financing. We may engage in additional equity and other financing transactions in order to raise funds. We may receive royalties and milestone payments under 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, 2025, we had cash, cash equivalents and marketable securities of $151.4 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.

Cash Flows

Cash and cash equivalents were $20.0 million as of December 31, 2025 compared to $24.6 million as of December 31, 2024. We also had $131.4 million in short- and long-term marketable securities as of December 31, 2025 compared to $179.3 million as of December 31, 2024.

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

	Year Ended December 31,	
(In thousands)	**2025**	**2024**
Cash and cash equivalents beginning balance	$ 24,570	$ 39,878
Net cash used in operating activities	(47,113)	(20,075)
Net cash provided by (used in) investing activities	48,365	(69,769)
Net cash (used in) provided by financing activities	(5,862)	74,536
Cash and cash equivalents ending balance	$ 19,960	$ 24,570

Operating Activities

Cash flow related to operating activities was the result of:

(In thousands)	Year Ended December 31, 2025	2024
Net loss	$ (64,923)	$ (132,065)
Non-cash adjustments to reconcile net loss to net cash used in operating activities	15,138	101,068
Change in accounts receivable, prepaid expenses and other assets	6,138	(4,875)
Change in accounts payable and accrued expenses	350	(8,130)
Change in deferred income	(3,816)	23,927
Net cash used in operating activities	$ (47,113)	$ (20,075)

Net cash used in operating activities increased for the year ended December 31, 2025 compared to the year ended December 31, 2024 primarily as a result of higher net losses after adjusting for non-cash items and proceeds from the royalty sale to OMERS during 2024. The change was partially offset by a decrease in cash used for accounts payable and accrued expenses, after adjusting for the receipt and corresponding payment of a third-party milestone during the year ended December 31, 2025.

The decrease 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 during the year ended December 31, 2024.

Investing Activities

Cash flow related to investing activities was the result of:

(In thousands)	Year Ended December 31, 2025	2024
Purchases of property and equipment	$ (111)	$ (121)
Purchases of marketable securities	(39,732)	(119,982)
Proceeds from sales and maturities of marketable securities	89,041	86,144
Payments of deferred transaction consideration for in-licensed assets	(833)	—
Acquisition of in-licensed assets, including transaction costs	—	(35,810)
Net cash provided by (used in) investing activities	$ 48,365	$ (69,769)

Net cash provided by investing activities for the year ended December 31, 2025 was $48.4 million compared to net cash used in investing activities during the year ended December 31, 2024 of $69.8 million. The change was primarily due to higher purchases of marketable securities and the consideration paid in connection with the in-license of bosakitug and ATI-052 during the year ended December 31, 2024.

Financing Activities

Cash flow related to financing activities was the result of:

(In thousands)	Year Ended December 31, 2025	2024
Proceeds from issuance of common stock under securities purchase agreement, net of issuance costs	$ —	$ 74,913
Payments of deferred transaction consideration for in-licensed assets	(5,416)	—
Payments of employee withholding taxes related to restricted stock unit award vesting	(446)	(409)
Proceeds from exercise of employee stock options and the issuance of stock	—	32
Net cash (used in) provided by financing activities	$ (5,862)	$ 74,536

Net cash used in financing activities for the year ended December 31, 2025 was $5.9 million compared to net cash provided by financing activities during the year ended December 31, 2024 of $74.5 million. The change was primarily due to proceeds from our private placement during the year ended December 31, 2024.

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, professional and legal 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, tariff policies, 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 may 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 studies 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 $2.5 million as of December 31, 2025.

Agreement and Plan of Merger with Confluence

We have agreed to certain payment obligations in accordance with and subject to the terms of the Confluence Agreement (see "Overview—Acquisition and License Agreements—Agreement and Plan of Merger with Confluence"). As of December 31, 2025, the balance of our contingent consideration liability was $11.0 million.

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

We have agreed to certain payment obligations in accordance with and subject to the terms of the Biosion Agreements (see "Overview—Acquisition and License Agreements—Exclusive License Agreement with Biosion").

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 operate and report as one reportable segment, which focuses on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases. The segment earns revenue through the licensing of our intellectual property and the provision of laboratory services. Our chief operating decision maker, our Chief Executive Officer, manages our operations on a consolidated basis for the purpose of making operating decisions, assessing financial performance, and allocating resources.

Recently Issued Accounting Pronouncements

In December 2025, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2025-12, "Interim Reporting (Topic 270): Narrow-Scope Improvements." This standard clarifies interim disclosure requirements and the applicability of Topic 270. The ASU becomes effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. We are currently assessing the impact of this ASU.

In November 2024, the FASB issued 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. We adopted ASU No. 2023-09 effective December 31, 2025, on a prospective basis, the impact of which is limited to additional income tax 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

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Aclaris Therapeutics, Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, 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, 2025 and 2024, 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 $11.0 million as of December 31, 2025. 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 26, 2026

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, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 19,960	$ 24,570
Short-term marketable securities	70,791	89,024
Accounts receivable, prepaid expenses and other current assets	5,565	12,357
Total current assets	96,316	125,951
Marketable securities	60,612	90,302
Property and equipment, net	761	1,008
Other assets	2,771	3,066
Total assets	$ 160,460	$ 220,327
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 13,158	$ 4,690
Accrued expenses	8,791	20,333
Deferred income	3,943	3,890
Other current liabilities	2,753	2,683
Total current liabilities	28,645	31,596
Other liabilities	1,565	4,439
Deferred income, net of current portion	16,168	20,038
Contingent consideration	11,000	8,700
Total liabilities	57,378	64,773
Stockholders' Equity:		
Preferred stock, $0.00001 par value; 10,000,000 shares authorized and no shares issued or outstanding at December 31, 2025 and December 31, 2024	—	—
Common stock, $0.00001 par value; 400,000,000 and 200,000,000 shares authorized at December 31, 2025 and December 31, 2024, respectively; 120,499,433 and 107,850,124 shares issued and outstanding at December 31, 2025 and December 31, 2024, respectively	1	1
Additional paid-in capital	1,070,255	1,058,317
Accumulated other comprehensive income	610	97
Accumulated deficit	(967,784)	(902,861)
Total stockholders' equity	103,082	155,554
Total liabilities and stockholders' equity	$ 160,460	$ 220,327

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,	
	2025	**2024**
Revenues:		
Contract research	$ 1,872	$ 2,541
Licensing	5,954	16,179
Total revenue	7,826	18,720
Costs and expenses:		
Cost of revenue	2,091	2,792
Research and development	52,645	33,586
General and administrative	21,972	22,203
Licensing	5,193	12,666
Revaluation of contingent consideration	2,300	2,500
In-process research and development	—	86,905
Total costs and expenses	84,201	160,652
Loss from operations	(76,375)	(141,932)
Other income:		
Interest income	7,637	7,953
Non-cash royalty income	3,815	1,914
Total other income	11,452	9,867
Net loss	$ (64,923)	$ (132,065)
Net loss per share, basic and diluted	$ (0.53)	$ (1.71)
Weighted average common shares outstanding, basic and diluted	122,564,741	77,296,665
Other comprehensive income:		
Unrealized gain on marketable securities, net of tax of $0	$ 513	$ 203
Total other comprehensive income	513	203
Comprehensive loss	$ (64,410)	$ (131,862)

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, 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
Issuance of common stock in connection with vesting of restricted stock units	1,367,359	—	(446)	—	—	(446)
Exercise of common stock purchase warrants	11,281,950	—	—	—	—	—
Unrealized gain on marketable securities	—	—	—	513	—	513
Stock-based compensation expense	—	—	12,384	—	—	12,384
Net loss	—	—	—	—	(64,923)	(64,923)
Balance at December 31, 2025	120,499,433	$ 1	$ 1,070,255	$ 610	$ (967,784)	$ 103,082

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (64,923)	$ (132,065)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	454	807
Stock-based compensation expense	12,384	10,856
Revaluation of contingent consideration	2,300	2,500
In-process research and development expense	—	86,905
Changes in operating assets and liabilities:		
Accounts receivable, prepaid expenses and other assets	6,138	(4,875)
Accounts payable	8,447	(4,188)
Accrued expenses and other liabilities	(8,097)	(3,942)
Deferred income	(3,816)	23,927
Net cash used in operating activities	(47,113)	(20,075)
Cash flows from investing activities:		
Purchases of property and equipment	(111)	(121)
Purchases of marketable securities	(39,732)	(119,982)
Proceeds from sales and maturities of marketable securities	89,041	86,144
Payments of deferred transaction consideration for in-licensed assets	(833)	—
Acquisition of in-licensed assets, including transaction costs	—	(35,810)
Net cash provided by (used in) investing activities	48,365	(69,769)
Cash flows from financing activities:		
Proceeds from issuance of common stock under securities purchase agreement, net of issuance costs	—	74,913
Payments of deferred transaction consideration for in-licensed assets	(5,416)	—
Payments of employee withholding taxes related to restricted stock unit award vesting	(446)	(409)
Proceeds from exercise of employee stock options and the issuance of stock	—	32
Net cash (used in) provided by financing activities	(5,862)	74,536
Net decrease in cash and cash equivalents	(4,610)	(15,308)
Cash and cash equivalents at beginning of period	24,570	39,878
Cash and cash equivalents at end of period	$ 19,960	$ 24,570
Supplemental disclosure of non-cash investing and financing activities:		
Additions to property and equipment included in accounts payable	$ 21	$ —
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 discovering and developing novel small and large molecule product candidates for immuno-inflammatory diseases. The Company's proprietary KINect drug discovery platform coupled with its integrated discovery approach to small and large molecules enables the Company to identify and advance product candidates designed to have superior target affinity, specificity and potency. The Company is seeking to identify and consummate transactions with third-party partners to further develop, obtain marketing approval for and/or commercialize its novel product candidates.

Liquidity

The Company's consolidated financial statements have been prepared on the basis of continuity of operations, realization of assets and the satisfaction of liabilities in the ordinary course of business. As of December 31, 2025, the Company had cash, cash equivalents and marketable securities of $151.4 million and an accumulated deficit of $967.8 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, tariff policies, 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 nature and size of 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 and comprehensive loss.

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. 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.

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 12). 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.

Discontinued Operations

As of December 31, 2025 and 2024, 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 Life Sciences, Inc. (now known as Aclaris Life Sciences, Inc.) ("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 judgment 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 and comprehensive loss.

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 (collectively referred to as "probability of success"), which are based on an asset's current stage of development and a review of existing clinical data. Probability of success assumptions ranged between 21% and 40% at December 31, 2025. 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. As of December 31, 2025, the discount rate ranged between 6.7% 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 11). 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 in-process research and development ("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. 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. 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 because 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 composed 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 considers its Chief Executive Officer to be its CODM.

Historically, the Company had concluded it operated as two reportable segments, therapeutics and contract research. In December 2025, the Company reevaluated its operating segments and concluded it operates and reports as one reportable segment. The Company's conclusion is based on changes to the discrete financial reporting information regularly provided to the CODM for the purpose of making operating decisions, assessing financial performance, and allocating resources. Certain prior year amounts have been reclassified to conform to the current year presentation. Such reclassifications had no effect on the previously reported results of operations or financial position.

The Company's reportable segment focuses on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases. The segment earns revenue through the licensing of its intellectual property and the provision of laboratory services. As of December 31, 2025 and 2024, all of the Company's assets were held in the United States.

Recently Issued Accounting Pronouncements

In December 2025, the FASB issued Accounting Standards Update ("ASU") No. 2025-12, "Interim Reporting (Topic 270): Narrow-Scope Improvements." This standard clarifies interim disclosure requirements and the applicability of Topic 270. The ASU becomes effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. The Company is currently assessing the impact of this ASU.

In November 2024, the FASB issued 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. The Company adopted ASU No. 2023-09 effective December 31, 2025, on a prospective basis, the impact of which is limited to additional income tax 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:

	December 31, 2025			
(In thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 16,302	$ —	$ —	$ 16,302
Marketable securities	—	131,403	—	131,403
Total assets	$ 16,302	$ 131,403	$ —	$ 147,705
Liabilities:				
Contingent consideration	$ —	$ —	$ 11,000	$ 11,000
Total liabilities	$ —	$ —	$ 11,000	$ 11,000

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

As of December 31, 2025 and 2024, the Company's cash equivalents consisted of money market funds, which were valued based upon Level 1 inputs. The Company's marketable securities as of December 31, 2025 consisted of corporate debt securities and U.S. government debt securities, which were all valued based upon Level 2 inputs. The Company's marketable securities as of December 31, 2024 consisted of commercial paper, corporate debt securities, foreign government agency debt securities, and U.S. government and government agency debt securities, which were all 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, 2025 and 2024, there were no transfers into or out of Level 3.

The overall $2.3 million increase in the fair value of the contingent consideration liability during the year ended December 31, 2025 was primarily due to changes to the probability of success for certain product candidates and the passage of time.

As of December 31, 2025 and 2024 the fair value of the Company's available-for-sale marketable securities by type of security was as follows:

(In thousands)	December 31, 2025 Book Value	Gross Unrealized Gain	Gross Unrealized Loss	Fair Value
Marketable securities:				
Corporate debt securities[1]	$ 85,222	$ 373	$ —	$ 85,595
U.S. government debt securities[2]	45,571	237	—	45,808
Total marketable securities	$ 130,793	$ 610	$ —	$ 131,403

(1) Included in Corporate debt securities is $45.4 million with maturity dates between one and three years.
(2) Included in U.S. government debt securities is $15.2 million with maturity dates between one and three years.

(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	$ 179,239	$ 255	$ (168)	$ 179,326

(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.

4. Accrued Expenses

Accrued expenses consisted of the following:

(In thousands)	December 31, 2025	December 31, 2024
Employee compensation expenses	$ 5,298	$ 4,979
Research and development expenses	1,612	2,173
Deferred transaction consideration	—	3,927
Licensing expenses	1,377	8,645
Other expenses	504	609
Total accrued expenses	$ 8,791	$ 20,333

5. Stockholders' Equity

Preferred Stock

As of December 31, 2025 and 2024, 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, 2025 and 2024.

Common Stock

On June 5, 2025, at the 2025 Annual Meeting of Stockholders, the Company's stockholders approved an amendment to the Charter to increase the authorized number of shares of common stock from 200,000,000 shares to 400,000,000 shares. On June 5, 2025, the Company filed a Certificate of Amendment to the Charter with the Secretary of State of the State of Delaware, which became effective upon filing.

As of December 31, 2025 and 2024, the Company's Charter authorized the Company to issue 400,000,000 and 200,000,000 shares of $0.00001 par value common stock, respectively. There were 120,499,433 and 107,850,124 shares of common stock issued and outstanding as of December 31, 2025 and 2024, 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, 2025.

Warrants

In November 2024, 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.

In December 2025, Biosion exercised 11,281,985 Warrants. As of December 31, 2025, 3,000,000 Warrants remained unexercised.

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.

6. Stock-Based Awards

2025 Equity Incentive Plan

In April 2025, the Company's board of directors adopted the 2025 Equity Incentive Plan (the "2025 Plan"), and in June 2025, the Company's stockholders approved the 2025 Plan. Upon the 2025 Plan becoming effective, no further grants can be made under the Company's 2015 Equity Incentive Plan (the "2015 Plan"). The 2025 Plan provides for the grant of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock awards, RSU awards, cash-based awards, and other stock-based awards. The number of shares initially reserved for issuance under the 2025 Plan was 25,532,993 shares of common stock, which includes (i) 9,000,000 new shares of common stock, (ii) 3,957,232 shares of common stock that remained available for future grant under the 2015 Plan upon adoption of the 2025 Plan and (iii) up to 12,575,761 shares of common stock underlying outstanding awards under the 2015 Plan and the former 2012 Equity Compensation Plan, which may become available for issuance under the 2025 Plan if and as such awards expire, are otherwise terminated, settled in cash, or repurchased by the Company. The shares of common stock underlying any awards that expire, or are otherwise terminated, settled in cash or repurchased by the Company under the 2025 Plan will be added back to the shares of common stock available for issuance under the 2025 Plan. As of December 31, 2025, 12,442,759 shares remained available for grant under the 2025 Plan. The Company had 1,007,910 stock options and 320,840 RSUs outstanding as of December 31, 2025 under the 2025 Plan.

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, RSU awards, 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, 2025, 493,500 shares remained available for grant under the 2024 Inducement Plan. The Company had 1,172,000 stock options and 302,500 RSUs outstanding as of December 31, 2025 under the 2024 Inducement 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 325,000 stock options outstanding as of December 31, 2025 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.

2015 Equity Incentive Plan

In September 2015, the Company's board of directors adopted 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. Upon the 2025 Plan becoming effective, no further grants can be made under the 2015 Plan. The Company had 8,764,489 stock options and 2,179,891 RSUs outstanding as of December 31, 2025 under the 2015 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, 2025 and 2024 were as follows:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	4.26 %	3.91 %
Expected term (in years)	6.2	6.0
Expected volatility	82.79 %	81.62 %
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, 2025 and 2024:

(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, 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
Granted	5,407,305	2.18		
Forfeited and cancelled	(859,873)	13.32		
Outstanding as of December 31, 2025	11,269,399	$ 6.72	7.7	$ 8,597
Options vested and expected to vest as of December 31, 2025	11,269,399	$ 6.72	7.7	$ 8,597
Options exercisable as of December 31, 2025	4,174,406	$ 12.72	5.8	$ 2,503

The weighted average grant date fair value of stock options granted during the years ended December 31, 2025 and 2024 was $1.61 and $1.34 per share, respectively.

Restricted Stock Units

The following table summarizes RSU activity for the years ended December 31, 2025 and 2024:

(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, 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	2,276,151	$ 5.12	
Granted	2,190,582	2.26	
Vested	(1,537,652)	4.26	$ 4,122
Forfeited and cancelled	(125,850)	4.31	
Outstanding as of December 31, 2025	2,803,231	$ 3.40	

Stock-Based Compensation

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

	Year Ended December 31,	
(In thousands)	2025	2024
Cost of revenue	$ 788	$ 938
Research and development	4,258	3,135
General and administrative	7,338	6,783
Total stock-based compensation expense	$ 12,384	$ 10,856

As of December 31, 2025, the Company had unrecognized stock-based compensation expense for stock options and RSUs of $11.1 million and $6.1 million, respectively, which is expected to be recognized over weighted average

periods of 2.5 years and 2.3 years, respectively.

7. 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, 2025	2024
Numerator:		
Net loss	$ (64,923)	$ (132,065)
Denominator:		
Weighted average shares of common stock outstanding, basic and diluted	122,564,741	77,296,665
Net loss per share, basic and diluted	$ (0.53)	$ (1.71)

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 years ended December 31, 2025 and 2024, the basic and diluted weighted average shares outstanding included the shares of common stock issuable upon exercise of the outstanding 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, 2025 and 2024. All share amounts presented in the table below represent the total number outstanding as of December 31, 2025 and 2024.

	Year Ended December 31, 2025	2024
Options to purchase common stock	11,269,399	6,721,967
Restricted stock units	2,803,231	2,276,151
Total potential shares of common stock	14,072,630	8,998,118

8. Leases

The Company has operating leases for office space and laboratory facilities. Rent expense was $0.8 million and $0.9 million for the years ended December 31, 2025 and 2024, respectively, which was recognized on a straight-line basis over the term of the lease.

Operating Leases

Agreements for Office and Laboratory Space

In May 2023, the Company entered into a lease agreement pursuant to which it leases 11,564 square feet of office space for its headquarters in Wayne, Pennsylvania. The lease commenced in November 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, 2025	December 31, 2024
Operating Leases:		
Gross cost	$ 4,530	$ 4,530
Accumulated amortization	(2,245)	(1,688)
Other assets	$ 2,285	$ 2,842
Current portion of lease liabilities	$ 551	$ 481
Other liabilities	1,565	2,117
Total operating lease liabilities	$ 2,116	$ 2,598

Amortization expense related to operating lease right-of-use assets and accretion of operating lease liabilities totaled $0.6 million and $0.5 million for the years ended December 31, 2025 and 2024, respectively.

Supplemental information related to operating leases is as follows:

(In thousands, except for years and percentages)	Year Ended December 31,	
Supplemental Cash Flow Lease Information:	**2025**	**2024**
Operating cash flows from operating leases	$ 755	$ 736
Weighted Average Remaining Lease Term (in years):		
Operating leases	3.3	4.3
Weighted Average Discount Rate:		
Operating leases	10.1 %	10.1 %

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

(In thousands) Year Ending December 31,	Operating Leases
2026	711
2027	760
2028	779
2029	260
Total undiscounted lease payments	2,511
Less: unrecognized interest	(395)
Total lease liability	$ 2,116

9. Income Taxes

During the years ended December 31, 2025 and 2024, 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, 2025	2024
U.S. operations	$ (64,923)	$ (132,065)
Foreign operations	—	—
Loss before income taxes	$ (64,923)	$ (132,065)

A reconciliation of the provision for income taxes to the amount computed by applying the 21% U.S. federal statutory income tax rate to income before income taxes after the adoption of ASU 2023-09 is as follows:

(In thousands, except percentages)	Year Ended December 31, 2025	
Federal taxes at U.S. statutory income tax rate	$ (13,634)	(21.0)%
Tax credits		
Research and development tax credits	(2,531)	(3.9)
Change in valuation allowance	14,366	22.1
Non-taxable or non-deductible items		
Non-deductible royalty payments	726	1.1
Other non-deductible items	1,073	1.7
Effective income tax rate	$ —	0.0 %

A reconciliation of the provision for income taxes to the amount computed by applying the 21% U.S. federal statutory income tax rate to income before income taxes for years prior to the adoption of ASU 2023-09 is as follows:

	Year Ended December 31, 2024
Federal statutory income tax rate	(21.0)%
State taxes, net of federal benefit	(2.1)
Impact of state rate changes	(1.1)
Research and development tax credits	(1.1)
Excess equity compensation tax benefit, net of officer limitation	0.8
Revaluation of contingent consideration	0.4
Non-deductible royalty payments	1.8
Change in deferred tax asset valuation allowance	22.1
Other	0.2
Effective income tax rate	(0.0)%

Deferred tax liabilities, net consisted of the following:

	December 31,	
(In thousands)	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 123,685	$ 120,361
Capitalized start-up costs	2,949	3,469
Research and development tax credit carryforwards	2,531	21,954
Section 174 research and development capitalization	21,396	31,185
Capitalized research and development expense	1,820	2,145
Stock-based compensation expense	20,093	19,101
Accrued compensation	796	791
Lease liabilities	474	588
Deferred income	4,536	5,510
IPR&D	19,534	20,004
Other	397	408
Total deferred tax assets	198,211	225,516
Deferred tax liabilities:		
Property and equipment	(31)	(56)
Right-to-use assets	(510)	(642)
Other	(559)	(458)
Total deferred tax liabilities	(1,100)	(1,156)
Valuation allowance	(197,111)	(224,360)
Deferred tax liabilities, net	$ —	$ —

As of December 31, 2025, the Company had federal and state net operating loss ("NOL") carryforwards of $568.2 million and $100.7 million, respectively, which will begin to expire in 2032. As of December 31, 2025, the Company also had federal research and development tax credit carryforwards of $2.5 million which will begin to expire in 2045.

Utilization of the NOLs and research and development tax credit carryforwards in the United States are subject to annual limitations under Section 382 of the Internal Revenue Code of 1986 due to ownership changes that have occurred previously or that could occur in the future. 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 completed an analysis under Section 382 for NOLs generated through December 31, 2024, and concluded that an ownership change occurred as of December 30, 2024. As a result of this ownership change a component of the Company's research and development credits and state NOL carryforwards will expire prior to utilization. Accordingly, the Company has recorded an adjustment to write down its research and development credit and state NOL deferred tax assets in the amount of $21.9 million and $19.0 million, respectively. The write down of these deferred tax assets resulted in a corresponding adjustment to the Company's valuation allowance.

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. These future ownership changes may limit the amount of carryforwards that can be utilized annually to offset future taxable income.

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, 2025 and 2024. 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, 2025 and 2024, which related primarily to the increases in NOLs, capitalized research and development costs, and research and development tax credit carryforwards, offset by decreases to deferred tax assets associated with research and development tax credits and state NOL carryforwards due to the Section 382 ownership change described above, were as follows:

	Year Ended December 31,	
(In thousands)	**2025**	**2024**
Valuation allowance at beginning of year	$ (224,360)	$ (195,124)
Decreases recorded as benefit to income tax provision	27,249	—
Increases recorded to income tax provision	—	(29,236)
Valuation allowance as of end of year	$ (197,111)	$ (224,360)

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 2022 to the present. All open years may be examined to the extent that tax credits 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, 2025 and 2024.

10. Related Party Transaction

In November 2024, 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.

11. 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", and together with the Biosion Agreement, the 'Biosion Agreements") with Biosion and CTTQ, a licensee of bosakitug in Greater China.

As partial consideration for the rights and licenses under the Biosion Agreements, the Company, in the aggregate, (i) paid $30.0 million in upfront cash consideration, plus $4.5 million for the reimbursement of certain development costs, (ii) issued the Warrants, and (iii) paid $6.2 million for the reimbursement of certain development costs and drug product material. The Company made cash payments of $6.2 million and $34.5 million as set forth in the Biosion Agreements during the years ended December 31, 2025 and 2024, respectively.

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.

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, regulatory and commercial milestone 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 $1.2 million and $3.0 million of licensing revenue during the years ended December 31, 2025 and 2024, respectively, a portion of which was payable to third parties.

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 the consideration received from Pediatrix is payable to the former Confluence equity holders as described below under the caption "—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, anniversary, regulatory and commercial milestone payments. In addition, Lilly has agreed to pay the Company other commercial milestone payments upon the achievement of specified milestones and additional anniversary payments as set forth in the agreement, as well as 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 12).

During the year ended December 31, 2025, the Company recognized licensing revenue of $4.8 million, all of which was payable to third parties. During the year ended December 31, 2024, the Company recognized licensing revenue of $13.2 million, a portion of which was payable to third parties. As of December 31, 2024, a receivable of $8.6 million was recognized in other current assets, which represents licensing revenue that was due to third parties.

Asset Purchase Agreement – EPI Health, LLC

In October 2019, the Company sold RHOFADE (oxymetazoline hydrochloride) cream, 1% ("RHOFADE") 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 RHOFADE 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 had been fully reserved. In September 2025, the Company sold all of its right, title and interest in its bankruptcy claims against EPI Health and wrote off the remaining reserved balance as it was deemed uncollectible.

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, 2025 and 2024, the balance of the Company's contingent consideration liability was $11.0 million and $8.7 million, respectively (see Note 3).

12. 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 payments 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. For the years ended December 31, 2025 and 2024, the Company recognized $3.8 million and $1.9 million of non-cash royalty income, respectively. As of December 31, 2025, the current and non-current portions of the remaining deferred income recognized under the units-of revenue method were $3.9 million and $16.2 million, respectively.

13. 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. During the year ended December 31, 2025, the Company made cash severance payments of $0.2 million to impacted employees. 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.

14. Segment Information

The Company operates and reports as one reportable segment, which focuses on identifying and developing innovative therapies to address significant unmet needs for immuno-inflammatory diseases. The segment earns revenue through the licensing of the Company's intellectual property and the provision of laboratory services. All customers and revenue pertaining to the reportable segment are based in the United States.

When evaluating the Company's financial performance, the CODM regularly reviews consolidated segment loss, total expense, and direct expenses by project. The CODM allocates resources based on the Company's available cash resources and forecasted expenditures on a consolidated basis. Segment asset information regularly provided to the CODM is consistent with that reported on the consolidated balance sheet with particular emphasis on the Company's available liquidity, including its cash, cash equivalents and marketable securities balances.

The following table presents the significant segment expenses and other segment items regularly reviewed by the CODM for the years ended December 31, 2025 and 2024:

(In thousands)	Year ended December 31, 2025	2024
Contract research	$ 1,872	$ 2,541
Licensing revenue	5,954	16,179
Total revenue	7,826	18,720
Cost of revenue	2,091	2,792
Research and development:[1]		
Bosakitug	13,845	299
ATI-052	7,074	1,895
ATI-2138	4,921	4,209
ATI-9494	5,371	2,360
Discovery	3,872	3,415
Total research and development project expenses	35,083	12,178
Personnel	11,816	11,446
Other research and development[2]	5,746	9,962
Total research and development	52,645	33,586
General and administrative[3]	21,972	22,203
Licensing	5,193	12,666
Revaluation of contingent consideration	2,300	2,500
In-process research and development	—	86,905
Segment operating loss	$ (76,375)	$ (141,932)
Other income	11,452	9,867
Segment loss before income taxes	$ (64,923)	$ (132,065)

(1) Research and development expenses primarily consist of direct costs incurred to specific programs, including costs to conduct clinical trials and to manufacture clinical drug supply.

(2) Other research and development expenses primarily consist of indirect costs incurred in support of overall research and development activities and non-specific programs, including activities that benefit multiple programs, as well as stock-based compensation.

(3) General and administrative expenses consist principally of salaries and related costs, including stock-based compensation, for personnel in executive, administrative, finance and legal functions, as well as facility-related costs, professional fees, business development costs, insurance costs, and travel expenses.

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, 2025, 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, 2025, 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, 2025 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, 2025 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

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

During the quarter ended December 31, 2025, none of our directors or officers (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).

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 9, 2026. There are no family relationships among any of our directors or executive officers.

For our directors, the biographies below include information, as of February 9, 2026, 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.

Name	Age	Position
Executive Officers:		
Neal Walker	56	Chief Executive Officer, Chair of the Board of Directors
Hugh Davis, Ph.D.	67	President, Chief Operating Officer and Director
Kevin Balthaser	39	Chief Financial Officer
Roland Kolbeck, Ph.D.	62	Chief Scientific Officer
James Loerop	62	Chief Business Officer
Jesse Hall	52	Chief Medical Officer
Non-management Directors:		
Christopher Molineaux	60	Lead Independent Director
Maxine Gowen, Ph.D.	67	Director
William Humphries	59	Director
Anand Mehra, M.D.	50	Director
Vincent Milano	62	Director
Andrew Schiff, M.D.	60	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 2028 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 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 received 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.

Roland Kolbeck, Ph.D.

Roland Kolbeck, Ph.D., has served as our Chief Scientific Officer since July 2025. He most recently served as Chief Scientific Officer for Spirovant Sciences from 2020 to April 2025, where he directed the company's strategy related to new indications, targets, and investments. Previously, Dr. Kolbeck was Vice President, Head of Respiratory, Inflammation and Autoimmune Research (RIA) at MedImmune, AstraZeneca's global biologics organization. Prior to Medimmune, he served in senior scientific roles at Peptimmune and Millennium Pharmaceuticals. Dr. Kolbeck received his M.S. and Ph.D. degrees at the University of Regensburg and Max Planck Institute for Neurobiology (now the Max Planck Institute for Biological Intelligence), in Munich, Germany.

James Loerop

James Loerop has served as our Chief Business Officer since January 2022. From 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 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.

Jesse Hall, M.D.

Jesse Hall, M.D. has served as our Chief Medical Officer since April 2025. He most recently served as Chief Medical Officer for AltruBio from September 2021 until April 2025. Prior to AltruBio, from 2018 to April 2021, Dr. Hall served as Chief Medical Officer and EVP of Scientific and Clinical Affairs at Sublimity Therapeutics. Prior to Sublimity, Dr. Hall served as Chief Medical Officer of Aristea Therapeutics, and prior to that in roles of increasing responsibility at companies including Ardea Biosciences (a wholly owned subsidiary of AstraZeneca), Amgen, and Abbott Laboratories. Dr. Hall received a B.A. degree from the University of San Diego, an M.D. degree from the University of Oklahoma College of Medicine and conducted his surgical training at the Medical College of Pennsylvania and Hahnemann 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 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 as the chair of the board of directors of the publicly held company Passage Bio, Inc. Within the past five years, Dr. Gowen served as a director of the publicly held companies Merus N.V., 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 2028 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 Alcami Corporation, a contract development and manufacturing organization. From May 2021 to May 2023, Mr. Humphries served as the Chief Executive Officer of lsosceles Pharmaceuticals Inc, a biotechnology company. From 2018 to 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 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. Within the past five years, Dr. Mehra served 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. Mr. 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 2028 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, 2025, our named executive officers ("NEOs") were:

Name	Position
Neal Walker	Chief Executive Officer
Kevin Balthaser	Chief Financial Officer
James Loerop	Chief Business Officer

Summary Compensation Table

The following table presents the compensation awarded to or earned by each of our NEOs for the years ended December 31, 2025 and 2024.

Name and Principal Position	Year	Salary ($)	Stock Awards ($)[1]	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)	Total ($)
Neal Walker[3]	2025	615,000	828,426	1,581,615	350,550	-	3,375,591
Chief Executive Officer	2024	477,431	170,400	421,586	372,396	3,322 [4]	1,445,135
Kevin Balthaser	2025	446,000	310,640	548,440	171,710	14,000 [5]	1,490,790
Chief Financial Officer	2024	444,000	247,800	179,003	217,560	13,800 [5]	1,102,163
James Loerop[6]	2025	416,000	336,800	520,146	160,160	14,000 [5]	1,447,106
Chief Business Officer							

(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 RSUs are described in "Item 8—Notes to Consolidated Financial Statements—Note 6".

(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 2025 are discussed 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 as Interim Chief Executive Officer and he was appointed as Chief Executive Officer in February 2025.

(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) The amount consists of company matching contributions to the executive's 401(k) plan account.

(6) Mr. Loerop was not one of our named executive officers during the year ended December 31, 2024 and, accordingly, only his compensation for the year ended December 31, 2025 is included in the Summary Compensation Table in accordance with SEC rules.

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 2025, 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, 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 2024 and 2025:

Name	Annual Base Salary ($) 2024	2025	Percentage Change
Neal Walker	500,000	615,000 (1)	23.0 %
Kevin Balthaser	444,000	446,000	0.5 %
James Loerop	402,917	416,000	3.2 %

(1) The increase was related to Dr. Walker's appointment as Chief Executive Officer in 2025 from Interim Chief Executive Officer in 2024.

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 2025, the target bonus for Dr. Walker was 60% of his base salary and the target bonus for Mr. Balthaser and Mr. Loerop 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. 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 2025, 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 corporate 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 2025, our Compensation Committee approved our 2025 corporate performance goals. These goals were divided into two primary categories: (a) research and development (75%) and (b) other corporate activities, including business development, financing, and legal, finance and compliance objectives (25%). The Compensation Committee also approved stretch performance goals in both the research and development and other corporate categories that, if earned, could increase the overall funding of the bonus plan up to a maximum of 140% of the corporate performance target score. In addition to the corporate performance goals described above, Dr. Walker evaluated the individual performance of each of Mr. Balthaser and Mr. Loerop, and recommended a level of achievement to the Compensation Committee. The individual goals for Mr. Balthaser and Mr. Loerop focused on contributions toward our corporate objectives, personal qualities necessary to effectively manage a team, solve problems and drive our business forward, cross-functional execution to improve processes and productivity, and the promotion of a culture of ethics and compliance. Dr. Walker recommended full credit for these individual objectives, which the Compensation Committee approved.

In early 2026, the Compensation Committee considered each of the 2025 corporate performance goals, as well as individual goals where applicable, and awarded Dr. Walker, Mr. Balthaser and Mr. Loerop 95%, 96% and 96% of their target bonuses, respectively, for the year ended December 31, 2025. 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.

In accordance with historical practices and the methodology described above, in February 2025 Dr. Walker, Mr. Balthaser and Mr. Loerop were granted an annual equity grant consisting of 253,900, 88,100 and 83,500 restricted stock units, respectively, and stock options to purchase 888,800 shares, 308,200 shares and 292,300 shares, respectively, in each case which vest in four equal installments on the first, second, third and fourth anniversaries of February 3, 2025, subject to the officer's continuous service as of the applicable vesting date. In addition, during 2024 certain executives expended considerable effort undertaking a strategic review of our business, the result of which included the licensing of bosakitug and ATI-052 creating a more diversified pipeline of strategic opportunities for the Company across various immunologic and respiratory indications, as well as an extended cash runway achieved through cost rationalization and the closing of a private placement for aggregate gross proceeds of $80.0 million. To reward such executives for their efforts, in January 2025 Dr. Walker, Mr. Balthaser and Mr. Loerop were granted an equity grant consisting of 88,333, 40,000 and 55,000 restricted stock units, respectively, in each case which 33% of the award vests on January 2, 2025, 33% of the award vests on January 2, 2026 and 34% of the award vests on January 2, 2027, subject to the officer's continuous service as of the applicable vesting date.

Clawback Policy

Under our 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, 2025

The following table provides information about outstanding equity awards held by each of our NEOs as of December 31, 2025.

	Option Awards					Stock Awards	
		Number of Securities Underlying Unexercised Options (#)					
Name	Type of Award	Exercisable	Unexercisable	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]
Neal Walker	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	2/29/2032		
	Option	497,000	—	1.20	1/31/2034		
	Option	—	888,800 [1]	2.40	2/2/2035		
	RSU					59,184 [2]	178,144
	RSU					253,900 [1]	764,239
Kevin Balthaser	Option	11,200	—	27.54	7/4/2027		
	Option	2,100	—	22.09	1/31/2028		
	Option	15,500	—	24.06	2/28/2031		
	Option	25,050	8,350 [3]	14.94	2/29/2032		
	Option	52,500	52,500 [4]	16.97	1/31/2033		
	Option	51,625	154,875 [5]	1.20	1/31/2034		
	Option	—	308,200 [1]	2.40	2/2/2035		
	RSU					2,375 [3]	7,149
	RSU					15,000 [4]	45,150
	RSU					44,250 [5]	133,193
	RSU					26,800 [2]	80,668
	RSU					88,100 [1]	265,181
James Loerop	Option	116,250	38,750 [6]	11.58	1/31/2032		
	Option	52,500	52,500 [7]	16.97	1/31/2033		
	Option	51,625	154,875 [5]	1.20	1/31/2034		
	Option	—	292,300 [1]	2.40	2/2/2035		
	RSU					11,250 [6]	33,863
	RSU					15,000 [7]	45,150
	RSU					44,250 [5]	133,193
	RSU					36,850 [2]	110,919
	RSU					83,500 [1]	251,335

(1) Of the unvested stock options and RSUs, one-fourth vested on February 3, 2026 and the remainder will vest in three equal installments on February 3, 2027, February 3, 2028 and February 3, 2029, subject to the officer's continued service through each applicable vesting date.

(2) Of the total shares underlying this RSU award, 33% vested on January 2, 2025, 33% vested on January 2, 2026 and the remainder will vest on January 2, 2027, subject to the officer's continued service through the vesting date.

(3) These unvested stock options and RSUs will vest on March 1, 2026, subject to the officer's continued service through the vesting date.

(4) Of the unvested stock options and RSUs, 50% vested on January 1, 2026 and the remainder will vest on January 1, 2027, subject to the officer's continued service through the vesting date.

(5) Of the total shares underlying this stock option award and RSU award, one-fourth vested on February 1, 2025, one-fourth vested on February 1, 2026 and the remainder will vest in two equal installments on February 1, 2027 and February 1, 2028, subject to the officer's continued service through each applicable vesting date.

(6) These unvested stock options and RSUs vested on February 1, 2026.

(7) Of the unvested stock options and RSUs, 50% vested on February 1, 2026 and the remainder will vest on February 1, 2027, subject to the officer's continued service through the vesting date.

(8) Based on the closing price of our common stock of $3.01 per share on December 31, 2025.

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. Walker, Mr. Balthaser and Mr. Loerop. Under the employment agreements, each of them is 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 Mr. Balthaser and Mr. Loerop, 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 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 the then-current base salary for a period of 18 months following termination for 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 Mr. Balthaser and Mr. Loerop, 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. 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. 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 which constitutes gross negligence or a material breach of his duty of loyalty; (iii) any material breach by him 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 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 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 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.

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.

Pursuant to the policy in effect for 2025, each non-employee director received an annual cash retainer of $40,000 for serving on our Board. The Lead Independent Director received an additional annual cash retainer of $25,000. The members of each of the Audit, Compensation and Nominating and Corporate Governance 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

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 2025 Plan with an aggregate grant date fair value (as calculated for financial reporting purposes) equal to the lesser of (a) $640,000 or (b) the fair value of 121,000 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. The shares subject to each stock option granted will vest in 36 equal monthly installments on the monthly anniversary of the grant date and the RSUs will vest in three equal installments on the first, second and third 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 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 2025 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 60,500 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. 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.

The sum of any cash or other compensation and the value (based on the grant date fair value) of awards granted to any non-employee director for services as a director during any fiscal year may not exceed $750,000.

On June 5, 2025, the date of our 2025 annual meeting of stockholders, each non-employee director then serving on our Board was granted a stock option to purchase 42,350 shares of common stock and 11,580 RSUs under our 2025 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 2025. Each of Dr. Walker, our Chief Executive Officer, and Dr. Davis, our President and Chief Operating Officer, is also a director but did not receive any additional compensation for his service as a director in 2025. 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	52,000	18,065	42,422	112,486
Anand Mehra, M.D.	60,000	18,065	42,422	120,486
Christopher Molineaux	81,500	18,065	42,422	141,986
Andrew Schiff, M.D.	40,000	18,065	42,422	100,486
Maxine Gowen, Ph.D.	47,500	18,065	42,422	107,986
Vincent Milano	60,000	18,065	42,422	120,486

(1) Reflects the aggregate grant date fair value for awards granted for the fiscal year ended December 31, 2025 calculated in accordance with FASB ASC Topic 718. For a discussion of valuation assumptions, see "Item 8—Notes to Consolidated Financial Statements—Note 6." 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, 2025, our non-employee directors held the following number of stock options and RSUs: Mr. Humphries, 123,175 stock options and 11,580 RSUs; Dr. Mehra, 105,175 stock options and 11,580 RSUs; Mr. Molineaux, 106,066 stock options and 11,580 RSUs; Dr. Schiff, 121,175 stock options and 11,580 RSUs; Dr. Gowen, 113,175 stock options and 11,580 RSUs; and Mr. Milano, 119,175 stock options and 11,580 RSUs.

(3) Consists of 11,580 RSUs granted on June 5, 2025. The RSUs will vest on June 5, 2026, subject to continuous service with us through that date.

(4) Consists of an option granted on June 5, 2025 to purchase 42,350 shares at an exercise price of $1.56 per share. This option vests in 12 equal monthly installments through June 5, 2026, subject to continuous service with us through each vesting date.

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.

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 9, 2026 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	11.8 %
Biosion, Inc.[3]	11,281,950	9.3
Entities associated with Vivo Capital LLC[4]	8,888,888	7.3
BlackRock, Inc.[5]	6,700,629	5.5
The Vanguard Group[6]	6,662,063	5.5
Named Executive Officers and Directors:		
Neal Walker[7]	3,175,338	2.6
Kevin Balthaser[8]	509,380	*
James Loerop[9]	602,335	*
Hugh Davis[10]	204,575	*
William Humphries[11]	170,816	*
Christopher Molineaux[12]	175,379	*
Anand Mehra[13]	834,114	*
Andrew Schiff[14]	583,706	*
Maxine Gowen[15]	149,045	*
Vincent Milano[16]	150,607	*
All current directors and executive officers as a group (12 persons)[17]	6,555,295	5.3

* 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 121,087,249 shares outstanding on February 9, 2026, 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 9, 2026 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/A filed on January 9, 2026 by Biosion, Inc. and Bonita Biotech (HK) Ltd. The principal business address of these entities 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 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.

(5) This information has been obtained from a Schedule 13G/A filed on January 21, 2026 by BlackRock, Inc. Various persons have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of these shares. The principal business address of BlackRock, Inc. is 50 Hudson Yards, New York, NY 10001.

(6) This information has been obtained from a Schedule 13G filed on July 29, 2025 by The Vanguard Group. The Vanguard Group's clients, including investment companies registered under the Investment Company Act of 1940 and other managed accounts, have the right to receive or the power to direct the receipt of dividends from, or the proceeds from the sale of, these shares. The principal business address of The Vanguard Group is 100 Vanguard Blvd., Malvern, PA 19355.

(7) Consists of (a) 1,543,886 shares of common stock and (b) 1,631,452 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(8) Consists of (a) 185,755 shares of common stock, (b) 321,250 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026 and (c) 2,375 shares of common stock underlying RSUs that will vest within 60 days of February 9, 2026.

(9) Consists of (a) 192,260 shares of common stock and (b) 410,075 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(10) Consists of (a) 45,425 shares of common stock and (b) 159,150 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(11) Consists of (a) 33,525 shares of common stock and (b) 137,291 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(12) Consists of (a) 57,956 shares of common stock and (b) 117,423 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(13) Consists of (a) 714,823 shares of common stock and (b) 119,291 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(14) Consists of (a) 434,455 shares of common stock owned directly by Aisling Capital IV, LP ("Aisling"), (b) 13,960 shares of common stock owned directly by Dr. Schiff and (c) 135,291 shares of common stock underlying options held directly by Dr. Schiff that are exercisable within 60 days of February 9, 2026. 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.

(15) Consists of (a) 21,754 shares of common stock and (b) 127,291 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(16) Consists of (a) 17,316 shares of common stock and (b) 133,291 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026.

(17) Consists of (a) 3,261,115 shares of common stock, (b) 3,291,805 shares of common stock underlying options that are exercisable within 60 days of February 9, 2026 and (c) 2,375 shares of common stock underlying RSUs that will vest within 60 days of February 9, 2026.

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, 2025:

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:			
2015 Equity Incentive Plan[1]	10,944,380	$ 5.75 [2]	—
2025 Equity Incentive Plan	1,328,750	1.34 [3]	12,442,759
Equity compensation plans not approved by security holders:			
2017 Inducement Plan[4]	325,000	$ 24.59	—
2024 Inducement Plan[5]	1,474,500	2.04 [6]	493,500
Total	14,072,630		12,936,259

(1) No additional further options or awards may be granted under the 2015 Equity Compensation Plan.

(2) Weighted average exercise price for the 2015 Plan gives effect to outstanding RSUs, which have no exercise price. Excluding the RSUs, the weighted average exercise price would be $7.18 per share.

(3) Weighted average exercise price for the 2025 Plan gives effect to outstanding RSUs, which have no exercise price. Excluding the RSUs, the weighted average exercise price would be $1.77 per share.

(4) For a description of the material terms of this plan, see "Item 8—Notes to Consolidated Financial Statements—Note 6—2017 Inducement Plan."

(5) For a description of the material terms of this plan, see "Item 8—Notes to Consolidated Financial Statements—Note 6—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 $2.57 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, 2024 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 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, 2025 and 2024 by PricewaterhouseCoopers LLP, our principal accountant.

	Fiscal Year Ended December 31,	
	2025	2024
Audit Fees	$ 577,120	$ 507,000

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 3.1 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on June 5, 2025).
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.
10.1+	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).
10.2+	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).
10.3+	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).
10.4+	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).

10.5+	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).
10.6+	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).
10.7+	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).
10.8+	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).
10.9+	2025 Equity Incentive 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 June 5, 2025).
10.10+	Form of Stock Option Grant Notice and Option Agreement used in connection with the Aclaris Therapeutics, Inc. 2025 Equity Incentive 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 June 5, 2025).
10.11+	Form of Restricted Stock Unit Grant Notice and Restricted Stock Unit Award Agreement used in connection with the Aclaris Therapeutics, Inc. 2025 Equity Incentive Plan (incorporated herein by reference to Exhibit 10.3 to the Registrant's Current Report on Form 8-K (File No. 001-37581), filed with the SEC on June 5, 2025).
10.12+	Tenth 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, 2025).
10.13+	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-206437), filed with the SEC on August 17, 2015).
10.14+	Employment Agreement, dated as of April 28, 2025, by and between the Registrant and Jesse Hall (incorporated herein by reference to Exhibit 10.3 to the Registrant's Quarterly Report on Form 10-Q (File No. 001-37581), filed with the SEC on May 8, 2025).
10.15+	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).
10.16+	Employment Agreement, effective as of July 28, 2025, by and between the Registrant and Roland Kolbeck (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 November 6, 2025).
10.17+	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).
10.18§+	Employment Agreement, dated as of February 26, 2025, by and between the Registrant and Neal Walker (incorporated herein by reference to Exhibit 10.21 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2025).
10.19+	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).
10.20^	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).

10.21^	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).
10.22	Amended and Restated Sales Agreement, dated February 27, 2025, by and among the Registrant, Leerink Partners LLC and Cantor Fitzgerald & Co. (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 27, 2025).
10.23 ^§	Exclusive License Agreement, dated as of November 18, 2024, by and between the Registrant and Biosion, Inc. (incorporated herein by reference to Exhibit 10.26 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2025).
10.24 ^§	Collaboration Agreement, dated as of November 18, 2024, by and among the Registrant, Biosion, Inc. and Chia Tai Tianqing Pharmaceutical Group, Co., Ltd. (incorporated herein by reference to Exhibit 10.27 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2025).
10.25^§	Form of Common Stock Purchase Warrant Agreement issued on November 18, 2024 (incorporated herein by reference to Exhibit 10.28 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 2025).
19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-37581), filed with the SEC on February 27, 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	Incentive Compensation Recoupment Policy (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 26, 2026

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
/s/ Neal Walker Neal Walker	Chief Executive Officer, and Chairman of the Board of Directors *(Principal Executive Officer)*	February 26, 2026
/s/ Kevin Balthaser Kevin Balthaser	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	February 26, 2026
/s/ Christopher Molineaux Christopher Molineaux	Lead Independent Director	February 26, 2026
/s/ Anand Mehra, M.D. Anand Mehra, M.D.	Director	February 26, 2026
/s/ William Humphries William Humphries	Director	February 26, 2026
/s/ Andrew Schiff Andrew Schiff	Director	February 26, 2026
/s/ Hugh Davis Hugh Davis	President, Chief Operating Officer and Director	February 26, 2026
/s/ Maxine Gowen Maxine Gowen	Director	February 26, 2026
/s/ Vincent Milano Vincent Milano	Director	February 26, 2026

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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

Roland Kolbeck, Ph.D
Chief Scientific Officer

Jesse Hall, M.D.
Chief Medical Officer

James Loerop
Chief Business Officer

STOCKHOLDER REFERENCE

Annual Meeting
The annual meeting of stockholders will be held virtually at www.virtualshareholdermeeting.com/ACRS2026, at 9:00 a.m. Eastern Time on Thursday, June 4, 2026.

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:

701 Lee Road
Suite 103
Wayne, PA 19087
Tel: 484-324-7933
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.

701 Lee Road • Suite 103 • Wayne, PA 19087
www.aclaristx.com