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

OR

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

For the transition period from to

Commission file number: 001-42143

Alumis Inc.

(Exact name of registrant as specified in its charter)

Delaware	**86-1771129**
(State of other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

280 East Grand Avenue
South San Francisco, CA 94080
(Address of Principal Executive Offices)
(650) 231-6625
(Registrant's telephone number)

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, $0.0001 Par Value per Share	**ALMS**	**The Nasdaq Global Select Market**

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 Section 15(d) of the 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 (§232.0405 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 an emerging growth company. See the 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 ☒

Based on the closing price as reported on the Nasdaq Global Select Market, the aggregate market value of the registrant's voting and non-voting common stock held by non-affiliates on June 30, 2025 (the last business day of the registrant's most recently completed second fiscal quarter) was approximately $183.2 million. Shares of common stock held by each executive officer and director and by each stockholder affiliated with a director or an executive officer have been excluded from this calculation because such persons may be deemed to be affiliates. This determination of affiliate status is not necessarily a conclusive determination for other purposes. As of March 12, 2026, the registrant had 123,139,425 shares of voting common stock, $0.0001 par value per share, and 4,059,908 shares of non-voting common stock, $0.0001 par value per share, outstanding.

Documents Incorporated by Reference

None.

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In this Annual Report on Form 10-K, unless otherwise stated or as the context otherwise requires, references to "Alumis," "the Company," "we," "us," "our" and similar references refer to Alumis Inc.

This Annual Report on Form 10-K also contains registered marks, trademarks and trade names of other companies. All other trademarks, registered marks and trade names appearing in this report are the property of their respective holders. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), that involve substantial risks and uncertainties. All statements, other than statements of historical facts contained in this Annual Report on Form 10-K, including statements regarding our future financial condition, business strategy and plans, and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements by the following words: "anticipate," "believe," "continue," "could," "estimate," "expect," "intend," "may," "ongoing," "plan," "potential," "predict," "project," "should," "will," "would," or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words.

These forward-looking statements involve 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 on Form 10-K, we caution you that these statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. Forward-looking statements in this Annual Report on Form 10-K include, but are not limited to, statements about:

- our plans to submit an NDA for envu in PsO (each as defined herein) in the second half of 2026;
- the potential for our product candidate envu to transform the treatment landscape for IL-23/IL-17—driven diseases as well as those driven by Type I interferon;
- the potential for envu to meaningfully elevate care for and effectively reduce the full burden of disease for patients with PsO;
- the timing of our topline readout in our LUMUS Phase 2b trial;
- our ability to obtain funding for our operations, including funding necessary to complete further development and any commercialization of our product candidates;
- our expectations regarding the potential benefits of our strategy, including with respect to the integration of operations, technologies and personnel associated with the ACELYRIN Merger (as defined herein);
- our plans relating to the research and development of our product candidates;
- developments related to our competitors and our industry, including the success of competing product candidates and therapies that are, or may become, available;
- details regarding our strategic vision and planned product candidate pipeline;
- our beliefs regarding the success, cost and timing of our product candidate development activities and current and future clinical trials and studies, including study design;
- the timing or likelihood of regulatory filings or other actions and related regulatory authority responses;
- the ability and willingness of various third parties to engage in research and development activities involving our product candidates, and our ability to leverage those activities;
- our expectations regarding the potential benefits from any existing or future license or collaboration agreements, including the receipt of potential co-development, milestone and royalty payments;

- our expectations regarding the ease of administration associated with our product candidates;
- our expectations regarding the patient compatibility associated with our product candidates;
- our beliefs regarding the potential markets for our product candidates and our ability to serve those markets;
- our beliefs regarding the potential of our product candidates to demonstrate differentiation from other approved therapies or therapies in development;
- the ability to obtain and, if approved, maintain regulatory approval of any of our product candidates, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our ability to commercialize any approved products;
- the rate and degree of market acceptance of any approved products;
- our ability to attract and retain key personnel;
- the accuracy of our estimates regarding our future revenue, as well as our future operating expenses, capital requirements and needs for additional financing;
- our ability to obtain, maintain, protect and enforce intellectual property protection for our product candidates and technology and not infringe, misappropriate or otherwise violate the intellectual property of others;
- regulatory developments in the United States and foreign countries;
- our expectations regarding the period during which we qualify as an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"), and a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act; and
- statements of belief and any statement of assumptions underlying any of the foregoing.

You should refer to the section titled "Risk Factors" in Part I, Item 1A. of this Annual Report on Form 10-K for a discussion of other 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 on Form 10-K will prove to be accurate.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this Annual Report on Form 10-K, and although we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted a thorough inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these 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. 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.

RISK FACTORS SUMMARY

Below is a summary of the material factors that make an investment in our securities speculative or risky. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this Risk Factors Summary, and other risks that we face, can be found below under the heading "Risk Factors" under Part I, Item 1A of this Annual Report on Form 10-K and should be carefully considered, together with other information in this Annual Report on Form 10-K, before making investment decisions regarding our securities.

- We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.

- Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients, the availability of competitive products and significant competition for recruiting participants in clinical trials.

- We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.

- Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

- Our clinical trials may reveal serious adverse events ("SAEs") and significant adverse events ("AEs") not seen in our preclinical studies or prior clinical trials and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of envudeucitinib (or "envu"), formerly known as ESK-001, A-005 or any future product candidates.

- We face competition from entities that have made substantial investments into the rapid development of competitor treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies and/or candidates under development in our current indications.

- We are subject to various risks related to the acquisition and integration of ACELYRIN (as defined herein).

- Our business is highly dependent on the success of our most advanced product candidate, envu, and we cannot guarantee that envu will successfully complete development, receive regulatory approval or be successfully commercialized. If we are unable to develop, receive regulatory approval for and ultimately successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

- The regulatory approval processes of the U.S. Food and Drug Administration (the "FDA") and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

- We are dependent on the services of our management team and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

- If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.

- We cannot ensure that patent rights relating to inventions described and claimed in our or any current or future licensors and licensees pending patent applications will issue or that patents based on our or any current or future licensors and licensees patent applications will not be challenged and rendered invalid and/or unenforceable.

- We have and may continue to form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may neither enter into, nor realize the benefits of, such alliances or licensing arrangements.

- Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

- Failure or perceived failure to comply with existing or future laws, regulations, contracts, self-regulatory schemes, standards, and other obligations related to data privacy or security (including security incidents) could harm our business. Compliance or the actual or perceived failure to comply with such obligations could increase our costs and otherwise negatively affect our operating results and business.

- We may have conflicts with any current or future licensors, licensees, collaborators or strategic partners that could delay or prevent the development or commercialization of our product candidates.

PART I

Item 1. Business

Overview

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. Our name, Alumis, captures our mission to enlighten immunology, and is inspired by the words "allumer"—French for illuminate—and "immunis"—Latin for the immune system.

We are a clinical stage biopharmaceutical company with an initial focus on developing our two Tyrosine Kinase 2 ("TYK2") inhibitors: envudeucitinib ("envu"), formerly known as ESK-001, a second-generation inhibitor that we are developing to maximize target inhibition and optimize tolerability, and A-005, a central nervous system ("CNS") penetrant allosteric TYK2 inhibitor. Envu is currently being evaluated in an ongoing Phase 2 open-label extension ("OLE") trial, as well as a Phase 3 long-term extension ("LTE") trial in patients with moderate-to-severe plaque psoriasis ("PsO"), and we plan to submit a New Drug Application ("NDA") for envu in PsO to the FDA in the second half of 2026. Envu completed enrollment in the pivotal Phase 3 ONWARD1 and ONWARD2 clinical trials in patients with PsO, and we reported positive topline results in the first quarter of 2026. In addition, envu is currently being evaluated in a Phase 2 clinical trial in patients with systemic lupus erythematosus ("SLE"), for which we expect to report topline results in the third quarter of 2026. We are currently evaluating additional immune-mediated disease indications for envu, beyond PsO and SLE, and for A-005 in CNS and peripheral diseases. In April 2024, we initiated our Phase 1 program of A-005 in healthy volunteers and reported initial results in December 2024. In addition, in connection with the ACELYRIN Merger (as defined below), we acquired lonigutamab, a subcutaneously delivered, monoclonal antibody targeting IGF-1R for the potential treatment of Thyroid Eye Disease ("TED"). We are continuing to evaluate the development program for lonigutamab and its potential differentiation in a capital efficient manner.

Alumis was incubated by Foresite Labs and incorporated on January 29, 2021, as a Delaware corporation under the name FL2021-001, Inc. FL2021-001, Inc.'s name was changed to Esker Therapeutics, Inc. in March 2021, and to Alumis Inc. in January 2022.

We utilize our proprietary precision data analytics platform, biological insights and team of experienced research and development experts to deepen our understanding of disease pathologies, accelerate research and development and increase the probability of clinical success. Our collective insights informed our selection of TYK2 as the target for our two lead programs. Beyond TYK2, our proprietary precision data analytics platform and drug discovery expertise have led to the identification of additional preclinical programs that exemplify our precision approach.

We recognize that patients living with immune-mediated diseases need alternatives to currently available therapies. Despite recent advances and innovations in the treatment of immune-mediated diseases, many patients continue to suffer, cycling through currently approved therapies while looking for a solution that alleviates the debilitating impact of their disease without life-limiting side effects.

Addressing the needs of these patients is why we exist. We are pioneering a precision approach that leverages insights derived from powerful data analytics to select the right target, right molecule, right indication, right patient, right endpoint and right combination to dramatically improve patient outcomes. We believe that combining our insights with an integrated approach to drug development will produce the next generation of treatments to address immune dysfunction.

ACELYRIN Merger

On February 6, 2025, we entered into an Agreement and Plan of Merger, and, on April 20, 2025, we entered into an Amendment to Agreement and Plan of Merger (collectively the "Merger Agreement") with ACELYRIN, Inc. ("ACELYRIN") and Arrow Merger Sub, Inc., a Delaware corporation and our direct wholly owned subsidiary ("Merger Sub"). Under the terms of the Merger Agreement, Merger Sub merged with and into ACELYRIN, with ACELYRIN continuing as our direct wholly owned subsidiary (the "ACELYRIN Merger"). The Merger Agreement was approved by the disinterested directors on our board of directors and the board of directors of ACELYRIN and was approved by the

stockholders of each company on May 13, 2025. On May 21, 2025 (the "Closing Date"), we completed the ACELYRIN Merger in a common stock transaction valued at approximately $238.1 million settled through the issuance of 48,653,549 shares of our common stock to acquire net assets with a fair value of $426.0 million. See Note 3 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Our Product Candidates and Pipeline

We are building a pipeline of molecules with the potential to address a broad range of immune-mediated diseases as monotherapy or combination therapies. Within our TYK2 franchise, we are developing our most advanced product candidate, envu, an allosteric TYK2 inhibitor for the treatment of PsO and SLE. We are developing our second TYK2 product candidate, A-005, as a CNS-penetrant allosteric TYK2 inhibitor, to offer the therapeutic benefit of TYK2 inhibition within the CNS for a broad range of neuroinflammatory and neurodegenerative diseases. In connection with the ACELYRIN Merger, we acquired lonigutamab, a subcutaneously delivered, monoclonal antibody targeting IGF-1R for the potential treatment of TED.

Our Strategy

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. As our driving principle, we are using our precision approach focused on the important drivers of immune dysfunction. We use our key insights to pursue our mission of significantly improving outcomes for patients. We select drug targets that have been previously validated by strong human genetic evidence and human clinical data.

The core components of our business strategy include:

- ***Maximize the opportunity presented by envu's differentiated pharmacological profile and breadth of potential indications.*** We believe that envu is a foundational asset that exemplifies our approach. Genetic and biologic data generated to date highlight the important role of TYK2 inhibition across multiple diseases where we have current clinical programs (PsO and SLE) and future clinical ambitions. We intend to expand clinical development of envu to additional therapeutic areas and indications where TYK2 inhibition and our differentiated profile have the potential to deliver significant improvements for patients.

- ***Expand our TYK2 franchise with A-005, our allosteric TYK2 inhibitor selected to penetrate the CNS to treat neuroinflammation.*** There is strong biological rationale for the involvement of TYK2 in neuroinflammatory and neurodegenerative diseases, as well as compelling genetic evidence for the role of TYK2 in MS. As a result, we believe TYK2 inhibition has potential utility in various neuroinflammatory and neurodegenerative diseases, including MS, Alzheimer's disease, amyotrophic lateral sclerosis ("ALS"), optic neuritis, neuromyelitis optica and Parkinson's disease.

- ***Discover and advance earlier-stage product candidates into clinical development.*** We intend to expand our pipeline of clinical-stage product candidates by identifying and developing earlier-stage assets. Utilizing our precision approach to address immune dysfunction, we have selected multiple additional targets to date, including interferon regulatory factor 5 ("IRF5"), across indications that are in various stages of development, from lead identification to lead optimization. These targets may enable development in a broad range of indications, either as a monotherapy or using a combination therapy approach with our TYK2 product candidate franchise.

- ***Leverage our precision approach to increase speed of development, probability of success and precision of therapy.*** We leverage our proprietary precision data analytics platform that integrates key genetic and translational insights, with the aim to design efficient and effective development paths at every stage of our pipeline. We believe this approach can bring forth transformative medications by following the science to inform the right target, right molecule, right indication, right patient, right endpoint and right combinations.

- ***Evaluate strategic collaborations to maximize the global impact of our product candidates.*** We plan to strategically evaluate potential partnerships to maximize the value of our lead programs and broader portfolio. We believe that our product candidates, indications, clinical data and data analytics make our company an

attractive partner. Given our scientific expertise and significant therapeutic depth, and the broad addressable populations of our product candidates, the right partner could help us expand the breadth of indications we pursue and increase our commercial reach.

Immune Dysfunction Overview

The immune system is a highly regulated and balanced system that has evolved to protect us from infection, recognize and neutralize harmful agents from the environment and fight disease. Dysfunctional immune responses, whether directed towards self or non-self or through unbalanced activation or regulation, can lead to inflammation, allergy, autoimmunity and development of chronic immune-mediated diseases. We are building immune insights from patient samples, incorporating genetic, genomic and proteomic learnings, and translating preclinical findings in an effort to therapeutically target dysfunctional immune mechanisms to improve outcomes for patients with immune-mediated diseases.

Role of TYK2 in Immunology

TYK2 is an intracellular tyrosine kinase protein within the broader Janus kinase ("JAK") family shown to play an essential role in mediating cytokine receptor signaling pathways in both innate and adaptive immunity. Cytokines are a group of proteins in the body that play an important role in boosting the immune system. TYK2 associates with a defined set of cytokine receptors expressed primarily on immune cells, such as IL-23, IL-12 and type I interferon ("IFN") receptors, distinct from other JAK family members. TYK2 functions to relay signals into the cell through phosphorylation of signal transducing and activators of transcription (STATs), to initiate a cascade of protein-signaling interactions resulting in cytokine-responsive gene transcription and cell activation, which drives downstream immune responses including Th17, IL-17 pathways, and type I IFN responsive genes that are known drivers of inflammation and immune mediated disease. Therapeutic inhibition of TYK2 and associated cytokine pathways, in particular IL-23/IL-17 and type I IFN, have been broadly validated to address immune dysfunction in immune-mediated diseases, such as psoriasis, psoriatic arthritis and SLE. TYK2 is expressed in circulating and tissue-resident immune cells, and is also active in CNS-resident immune cells, such as microglia, which are thought to play a key role in neuroinflammation.

Human genetic studies of TYK2 strongly validated it as a therapeutic target. An identified loss-of-function mutation ("P1104A") in the TYK2 gene, present in approximately 3% to 5% of European populations, is protective against an array of immune-mediated disorders, including SLE, psoriasis, sarcoidosis, psoriatic arthritis, inflammatory bowel disease and neuroinflammatory and neurodegenerative conditions, such as MS. Importantly, this TYK2 variant does not appear to significantly increase susceptibility to serious infections. We believe that TYK2 inhibition as a targeted therapy may have an improved risk to benefit profile as compared to broad immune suppression.

TYK2 inhibition represents a breadth of opportunity, and there have been or are ongoing clinical trials of TYK2 inhibitors in multiple indications such as psoriatic arthritis, SLE, cutaneous lupus, alopecia areata, Sjogren's disease, vitiligo, Crohn's disease and ulcerative colitis.

Our TYK2 Franchise

Envu: Our Allosteric TYK2 Inhibitor

Envu is a potent, highly selective, allosteric TYK2 inhibitor.

Key Differentiating Features

We believe envu is differentiated from first-generation TYK2 inhibitors for the following reasons:

- **Intrinsic Selectivity and Preclinical Pharmacology**. Due to envu's design as an allosteric inhibitor, the molecule is both potent and intrinsically selective for TYK2 over other protein kinases, including the related JAK family members. No JAK-related pharmacology has been observed with envu to date.

- **Optimized Molecular Properties and Pharmacokinetics ("PK")**. At the core of envu's differentiation from

other clinical-stage allosteric inhibitors of TYK2 are its physicochemical properties that we believe impart highly desirable drug-like features. Envu is highly permeable with low efflux resulting in high and rapid systemic absorption and favorable tissue distribution *in vivo*. These properties result in its highly predictable, linear PK profile in humans with low variability. In addition, envu has a desirable half-life in humans of approximately 8 to 12 hours and we have not observed any concerns for drug-drug interactions with other therapies.

- **Maximal Target Inhibition.** Envu demonstrated a robust and predictable PK/PD relationship in Phase 1 studies, enabling the identification of a dose level that achieved maximal TYK2 inhibition for 24 hours a day to take into Phase 2 clinical trials. We define maximal inhibition as reaching the plateau of biological inhibition in the assay readout with no further impact seen with higher drug concentrations. At the 40 mg BID dose, maximal TYK2 inhibition was confirmed in healthy volunteer and PsO patient blood samples by RNA-seq analysis, and a return to non-lesional baseline levels of TYK2 pathway (including IFN signature, IL-23, IL-17) and PsO-relevant disease biomarkers was confirmed in PsO patient skin biopsies.

- **Clinical Tolerability.** There have been no clinically limiting findings across our clinical trials to date that prevent envu from being dosed to achieve maximal target inhibition. In contrast to what has been reported with first-generation allosteric TYK2 inhibitors, skin rashes have been observed at much lower frequency with envu to date, even at very high and sustained levels of target inhibition, suggesting that skin toxicities may not be an on-target, class effect of TYK2 inhibitors.

Strategic Indication Selection

TYK2-mediated cytokine signaling is involved in a broad range of immune-mediated diseases. TYK2 loss-of-function mutations have been shown to be protective for several conditions including psoriasis, psoriatic arthritis, Crohn's disease, ulcerative colitis and MS. Therefore, envu has the potential to provide benefit in a large number of indications. We have selected PsO and SLE as our initial indications.

Combination Potential

Despite significant advances in the treatment of immune-mediated disease, in many diseases, only a minority of patients achieve disease remission or nearly complete response with current therapies. Because of the complexity, overlap and redundancy of inflammatory pathways, combination approaches targeting complementary pathways may be needed to achieve high-hurdle endpoints such as remission. We believe that envu's pharmacological properties, including its lack of drug-drug interaction potential and its clinical profile, positions it well as a partner for future combination therapies.

Development

Envu is currently being evaluated in an ongoing Phase 2 open-label extension trial, as well as a parallel Phase 3 LTE trial in patients with PsO, as well as in a Phase 2b clinical trial in SLE.

Envu for the Treatment of PsO

Psoriasis is a chronic immune-mediated skin disease characterized by abnormal epidermal growth, usually presenting as red, scaly patches, papules or plaques (plaque psoriasis). Patients with psoriasis are also at increased risk of developing other co-morbid conditions, such as cardiovascular disease, obesity, insulin resistance, uveitis, arthritis and thyroid dysfunction. According to the World Health Organization, psoriasis significantly impacts quality of life—physical and emotional challenges of disfiguration, low self- esteem, loss of productivity and depression.

On January 6, 2026 we announced positive topline results from our Phase 3 ONWARD1 and ONWARD2 global Phase 3, multi-center, randomized, double-blind placebo-controlled clinical trials, evaluating envu in patients with PsO. Envu met all primary and secondary endpoints with high statistical significance in both trials. In each of these trials, envu achieved superior skin clearance compared with placebo ($p < 0.0001$) on the co-primary endpoints of Psoriasis Area and Severity Index ("PASI") 75, and static Physician's Global Assessment ("sPGA") 0/1 at Week 16. On average across both ONWARD1 and ONWARD2, 74% of patients achieved PASI 75 and 59% of patients achieved sPGA 0/1, with responses

deepening over time. Rapid responses were observed, with clear separation from placebo on PASI 90 as early as Week 4. At Week 24, on the higher hurdle skin clearance measures, approximately 65% of patients achieved PASI 90 and more than 40% achieved PASI 100, on average across both trials. In addition, consistent and clinically meaningful improvements across patient-reported outcomes relating to itch and quality of life were observed. Envu also achieved superior skin clearance compared with apremilast in each trial ($p<0.0001$) on all PASI endpoints at Week 24. We also announced that treatment with envu was generally well tolerated through Week 24 in both trials, with a safety profile consistent with our Phase 2 trial for envu in PsO, including the LTE trial. Treatment-emergent adverse event ("TEAE") frequency and severity were similar across ONWARD1 and ONWARD2, with the majority being mild to moderate, transient, and responding to standard therapy, if required. The most common TEAEs were headaches, nasopharyngitis, upper respiratory tract infections, and acne. No safety signals were observed. See "—Safety Profile of Envu" below for further information.

We plan to submit an NDA for envu in PsO to the FDA in the second half of 2026.

Envu for the Treatment of SLE

SLE is a chronic autoimmune disease predominantly affecting women at childbearing age. Clinical manifestations are highly heterogeneous, and the disease typically waxes and wanes, with flares and periods of relative remission. Certain loss-of-function variants of TYK2 significantly decrease the risk of SLE. While mortality in SLE has decreased since the mid-20th century as a result of improved treatments, the disease remains associated with increased disability and loss of social and occupational functioning and high utilization of health care resources.

We are currently conducting LUMUS, a Phase 2b, 48-week, global, placebo-controlled, double-blind, randomized, clinical trial evaluating envu in patients with moderate-to-severe active SLE, in the United States, Europe, the United Kingdom ("UK"), Latin America and Asia-Pacific ("APAC") countries. The primary endpoint in Part A of such trial is BILAG-Based Composite Lupus Assessment response (a validated composite measure of lupus disease activity) at Week 48. Eligible patients may enroll in Part B (an OLE) or participate in a four-week follow-up period.

Safety Profile of Envu

Envu has been administered to more than 2,000 participants and in some cases administered for up to three years. Envu has been generally well-tolerated in our Phase 2 STRIDE and OLE and Phase 3 ONWARD clinical trials to date, with the majority of AEs observed in such clinical trials having been graded mild-to-moderate in severity. As of December 31, 2025, the most common AEs reported by patients across active (envu) trial arms were headaches, upper respiratory tract infections, nasopharyngitis and acne, and the most common AEs deemed related to study drug by the principal investigator included headaches, upper respiratory tract infections, nasopharyngitis, rash and nausea. The safety profile of envu continues to be evaluated in our ongoing Phase 2 OLE in PsO, Phase 3 LTE trial in PsO, and our Phase 2b trial in SLE.

Envu is an allosteric inhibitor of TYK2. TYK2 is an intracellular tyrosine kinase protein shown to play an essential role in mediating cytokine receptor signaling pathways in both innate and adaptive immunity. Cytokines are a group of proteins in the body that play an important role in boosting the immune system. Other TYK2 inhibitors, such as deucravacitinib (marketed as Sotyktu which is approved for the treatment of adults with PsO), have shown AEs such as hypersensitivity reactions, infections, tuberculosis, malignancy and rhabdomyolysis. The label for deucravacitinib includes a warning concerning the potential for JAK-related adverse events, such as cardiovascular and thrombotic events. Given our similar mechanism of action, we closely monitor and characterize these potential safety risks in our clinical studies. We have observed and expect to continue to observe that additional AEs and SAEs, consistent with known side effects of TYK2 inhibition, may emerge in our ongoing and future clinical trials of envu, and we have also observed and expect to continue to observe trial participant withdrawals or discontinuations due to AEs.

A-005: Our CNS-Penetrant Allosteric TYK2 Inhibitor

The second clinical product candidate in our TYK2 franchise, A-005, is a highly differentiated, CNS-penetrant, allosteric TYK2 inhibitor that has potential applications in multiple sclerosis and other neurological diseases. as well as peripheral diseases. A loss-of-function mutation in the TYK2 gene has been shown by our proprietary genetic data set as well as scientific literature, to reduce the risk of developing MS. We are currently evaluating indications for our A-005 program

and intend to provide an update on an A-005 Phase 2 trial commencement following completion of this evaluation.

Role of TYK2 in Neuroinflammatory and Neurodegenerative Diseases

TYK2 pathways are active in CNS-resident immune cells and may play a localized role in the CNS contributing to the pathology of several CNS inflammatory disorders, including MS. Genome-wide association studies ("GWAS") have shown the loss-of-function TYK2 genetic variant, P1104A, has a protective effect for the development of MS. An additional missense variant in TYK2, Rs35018800, has the largest effect on MS risk of any variant outside the MHC/HLA region discovered to date. In addition to its genetic association with MS, TYK2 is known to be expressed and functionally active in CNS-resident microglia. Microglia express IL-23 and interferon receptors and IL-23/IL-12 cytokines have been shown to localize to MS lesions. Activated microglia are associated with disease worsening in MS, and TYK2 inhibitors with adequate CNS exposure may provide an opportunity to target neuroinflammation and neurodegeneration. We believe TYK2 inhibition has the potential to treat the neuroinflammatory component of other neurodegenerative diseases where activated microglia and/or TYK2 proinflammatory cytokines including interferon are implicated such as Alzheimer's disease, ALS, optic neuritis, neuromyelitis optica, and Parkinson's disease.

Development

A-005 for the Treatment of MS

MS is a chronic immune-mediated disease of the central nervous system. This condition causes a wide range of physical and cognitive challenges for those afflicted, often resulting in neurological symptoms and disabilities. Despite available treatments to manage symptoms and slow disease progression, treatments are limited for progressive disease and a definitive cure remains elusive. Agents directly targeting the CNS pathology and CNS resident cells, including activated microglia, are of increasing interest as these are thought to impact progressive neurological impairment. The unmet need lies in finding safe and more effective targeted therapies that can halt or reverse disease progression, alleviating the burden on patients and their families and improving their overall quality of life.

In December 2024, we announced positive data from a Phase 1 clinical trial evaluating the safety, tolerability and PK of single- and multiple-ascending doses of A-005 in healthy participants. In the clinical trial, A-005 was well tolerated with no SAEs reported.

Our Lonigutamab (IGF-1R Monoclonal Antibody) Program

Lonigutamab is a subcutaneously delivered, monoclonal antibody targeting IGF-1R for the treatment of TED, a potentially vision-threatening progressive autoimmune ocular disease in which the eye muscles, eyelids, tear glands and fatty tissues behind the eye become inflamed.

ACELYRIN announced data from its Phase 1/2 dose ranging trial of lonigutamab in TED in March 2024 and January 2025. We are continuing to evaluate the development program for lonigutamab and its potential differentiation in a capital efficient manner.

Our Discovery Programs

We are building a pipeline of molecules with the potential to address a broad range of immune-mediated diseases. We pursue drug targets that have been previously validated by strong human genetic evidence or human clinical data. Our drug discovery efforts for our selected targets take advantage of structure-guided approaches built from public or proprietary crystallographic structures to enable use of advanced computational methods. These approaches enable optimization of traditional protein modulators, protein degraders, and targeted covalent inhibitors as appropriate. In addition, we have chosen targets that could be complementary for use in combination with our existing TYK2 franchise and to each other.

For example, IRF5 is a transcription factor that mediates signaling of several cytokines including type I IFN, IL-6, IL-12, IL-23, and TNF. It is a genetically supported target across multiple immune indications with known functional roles in

both innate and adaptive immunity. IRF5 has been implicated in macrophage polarization, cell growth regulation, and apoptosis. It acts on innate immune responses via recognition of upstream self-nucleic acid-containing immune complexes and pathogens by toll like receptors ("TLR"), specifically: TLR7, TLR8 and TLR9 in the endosome via MyD88. Translocation of IRF5 to the nucleus following phosphorylation by IKKβ is critical to the pathogenesis of many immune mediated diseases. Genome-wide association studies have identified several functional genetic variants in IRF5 that predispose patients to immune-mediated diseases including, but not limited to SLE, systemic sclerosis, and primary sclerosing cholangitis.

We are actively engaged in lead generation activities to identify small molecules that can precisely bind and block IRF5 function. These efforts are aided by our proprietary crystal structure of our compounds bound to IRF5, which enables computational approaches to optimize binders for either IRF5 inhibition or degradation. We have developed several proprietary assays including a biochemical dimerization assay that has been used in conjunction with high-throughput screening to identify leads. In addition, we have applied an orthogonal method to identify small-molecule binders that may target allosteric pockets providing inhibition directly or as a component in a proteolysis-targeting chimera. We will pursue multiple mechanisms of inhibition and use our extensive pharmacology expertise to guide the final selection of clinical candidates.

Foresite Labs Services Agreement

Foresite Labs, LLC ("Foresite Labs") was an original stockholder in, and actively involved in our incubation. We and Foresite Labs have had an ongoing services agreement since our inception, with Foresite Labs originally providing incubation services, development assistance and oversight, and data analytics services; currently, Foresite Labs provides data analytics services related to our TYK2 franchise, our discovery programs and to our business development activities. The original Services Agreement between us and Foresite Labs was entered into in January 2021, was amended and restated in August 2021, was amended and restated for a second time in December 2023, and expires in December 2026, unless terminated earlier by the parties. Work under the Services Agreement is memorialized in a series of Statements of Work and we pay Foresite Labs for the estimated costs of its services in advance on a quarterly basis, with a true-up to actuals at the end of each quarter.

Intellectual Property

We strive to protect and enhance the proprietary technology, inventions and improvements that are commercially important to our business, including by seeking, maintaining, enforcing and defending patent rights. Our policy is to seek to protect our proprietary position by, among other methods, filing patent applications in the United States and in jurisdictions outside of the United States related to our proprietary technology, inventions, improvements and product candidates that are important to the development and implementation of our business. We also rely on trade secrets and know-how relating to our proprietary technology, assays and product candidates, and may in the future rely on in-licensing opportunities, to develop, strengthen and maintain our proprietary position in our field. Our commercial success will depend in part on our ability to obtain and maintain patent and other proprietary protection for our technology, inventions and improvements; to preserve the confidentiality of our trade secrets; to obtain and maintain any future licenses to use intellectual property owned by third parties; and to defend and enforce our proprietary rights, including our patent rights.

As of December 31, 2025, our solely owned patent portfolio included five issued U.S. patents, three pending U.S. provisional patent applications, over ten pending non-provisional U.S. patent applications, and over twenty granted foreign patents.

Envu and A-005

In regard to envu and A-005, we own one patent family with claims directed to composition of matter and methods of use that includes five issued U.S. patents, one pending U.S. patent application, over fifteen granted foreign patents in Europe (each validated in over 35 countries), and certain other countries, and over 10 foreign patent applications pending in various jurisdictions, such as Europe and Japan. Not accounting for any patent term adjustment or extensions or terminal disclaimers, and assuming that all applicable annuity and/or maintenance fees are paid timely, the issued patents, and, if granted, the pending patent applications in this family, are expected to expire in 2039.

We also own three patent families with claims directed to crystalline and salt forms of envu, which includes three pending U.S. applications, and over 30 foreign patent applications pending in various jurisdictions such as Europe and Japan. Not accounting for any patent term adjustment or extension and assuming that all applicable annuity and/or maintenance fees are paid timely, the patent applications, if issued, and any patent applications claiming the benefit of these PCT applications, if issued, will be expected to expire in 2043.

We own one patent family with claims directed to methods of treating a TYK2-mediated disease using envu, that includes a pending U.S. application and over 10 foreign applications pending in various jurisdictions such as Europe and Japan. Not accounting for any patent term adjustment or extension and assuming that all applicable annuity and/or maintenance fees are paid timely, any patent applications, if issued, will be expected to expire in 2043.

We own three additional patent families that disclose and/or contain claims directed to methods of treating various diseases with envu that include two pending U.S. non-provisional applications, four pending foreign applications and one pending U.S. provisional application. Not accounting for any patent term adjustment or extension and assuming that all annuity and/or maintenance fees are paid timely, patent applications from these patent families, if issued, will be expected to expire between 2044 and 2046.

We own three pending PCT applications and three additional foreign applications with claims directed to crystalline and salt forms of A-005, one pending PCT application and one additional foreign application with claims directed to methods of treating various diseases with A-005, one pending PCT application and one additional foreign application with claims directed to processes for making envu, and one pending PCT application and one additional foreign application with claims directed to formulations of envu. Not accounting for any patent term adjustment or extension and assuming that all applicable annuity and/or maintenance fees are paid timely, any patent applications claiming priority to the provisional applications, if issued, will be expected to expire in 2045.

We intend to pursue, in the normal course of business and when possible, composition, method of use, process, dosing and formulation patent protection for the product candidates we develop and commercialize. We may also pursue patent protection with respect to manufacturing and immunotherapy development processes and technology. When available to expand market exclusivity, we intend to strategically obtain or license additional intellectual property related to current or contemplated product candidates.

Lonigutamab

As of December 31, 2025, we exclusively in-licensed from Pierre Fabre Medicament SAS ("Pierre Fabre") two issued U.S. patents, over 55 corresponding foreign patents and 5 foreign patent applications directed to composition of matter. Such issued patents are expected to expire in 2035, without taking into account any possible patent term adjustment or extensions and assuming payment of all appropriate fees. The portfolio further includes 12 pending patent applications directed primarily to formulations and methods of use. Patents, if issued from these pending applications are expected to expire in 2043 or 2045, respectively, without giving effect to any potential patent term extensions and patent term adjustments, and assuming payment of all appropriate fees.

For more information regarding the risks related to our intellectual property, see Item 1A. "Risk Factors — Risks Related to Intellectual Property."

Sales and Marketing

Given our stage of development, we have not yet established a full commercial organization or distribution capabilities. We have stage-appropriate commercial capabilities and we intend to build a commercial infrastructure to support sales of any approved products. We also intend to continue evaluating opportunities to work with partners that enhance our capabilities with respect to the development and commercialization of our product candidates, if approved. In addition, we intend to commercialize our product candidates, if approved, in key markets in the United States, the European Union ("EU") and APAC, either alone or with partners in order to maximize the worldwide commercial potential of our programs.

Manufacturing

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. To date, we have obtained active pharmaceutical ingredients ("API") for envu and A-005 for our preclinical and clinical testing from different third-party API manufacturers and bulk drug product from other third-party manufacturers. We obtain our preclinical and clinical supplies from these manufacturers on a purchase order basis and currently do not have long-term supply arrangements in place. Our principal suppliers of critical raw materials are located in India and in Taiwan. We are in the process of implementing a redundant supply chain for envu API, drug product and critical raw material. For all our product candidates, we intend to identify and qualify redundant manufacturers to provide the API and drug product and prior to submission of the NDA to the FDA and/or a marketing authorization application to the European Medicines Agency ("EMA") and/or other health authorities. envu and A-005 are compounds of low molecular weight, generally called small molecules. Envu can be manufactured in reliable and reproducible processes from readily available starting materials. A-005 has been produced in small quantities to support our preclinical studies and is currently being manufactured at larger quantities for clinical testing. The chemistries for envu and A-005 are amenable to scale-up and do not require unusual equipment in the manufacturing process. Additional contract manufacturers are used to package, label, and distribute investigational drug products. This strategy allows us to maintain a more efficient infrastructure, avoid depending on our own manufacturing facility and equipment while simultaneously enabling us to focus our expertise on developing our products. We expect to continue to develop product candidates that can be produced cost-effectively at contract manufacturing facilities.

Competition

The biopharmaceutical industry is characterized by intense competition and rapid innovation. Our potential competitors include large pharmaceutical and biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our potential competitors have greater financial and technical human resources than we do, as well as equal or greater experience in the discovery and development of product candidates, obtaining FDA and other regulatory approvals of products and the commercialization of those products. Accordingly, our potential competitors may be more successful than us in achieving regulatory approvals and commercializing their drugs. We anticipate that we will face intense and increasing competition from existing, approved drugs, as well as new drugs entering the market and emerging technologies that become available. Finally, the development of new treatment methods for the diseases we are targeting could render our product candidates non-competitive or obsolete.

We believe the key competitive factors that will affect the development and commercial success of our product candidates, if approved, will be efficacy, safety, tolerability profile, convenience of dosing, price and coverage by governmental and third-party payors.

We are currently developing envu for the treatment of PsO and SLE, with multiple other potential indications to follow. Other emerging and established life sciences companies have been focused on similar therapeutics. If approved, envu would compete with several currently approved or late-stage oral clinical therapeutics in each such indication as well as other drugs used to treat such patients.

Our second TYK2 product candidate, A-005, is a highly differentiated CNS-penetrant allosteric TYK2 inhibitor that has a potential application in MS and other neuroinflammatory diseases. In MS, there are a large number of therapies available for the treatment of relapsing forms of MS, including interferon beta regulators, monoclonal antibodies, synthetic immunomodulatory drugs, and S1P receptor modulators.

Coverage and Reimbursement

Successful sales of approved drug products in the U.S. market will depend, in part, on the extent to which such drugs will be covered by third-party payors, such as government health programs or private health insurance (including managed care plans). Patients who are provided with prescriptions as part of their medical treatment generally rely on such third-party payors to reimburse all or part of the costs associated with their prescriptions and therefore adequate coverage and reimbursement from such third-party payors are critical to new and ongoing product acceptance. Coverage and

reimbursement policies for drug products can differ significantly from payor to payor as there is no uniform policy of coverage and reimbursement for drug products among third-party payors in the United States. There may be significant delays in obtaining coverage and reimbursement as the process of determining coverage and reimbursement is often time consuming and costly. Further, third-party payors are increasingly reducing reimbursements for medical drugs and services and implementing measures to control utilization of drugs (such as requiring prior authorization for coverage).

Additionally, the containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic drugs. For example, the U.S. Department of Health and Human Services ("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 years and biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 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. Adoption or expansion of price controls and cost-containment measures could further limit manufacturers' net revenue and results. Decreases in third-party reimbursement for a manufacturer's drug products or a decision by a third-party payor to not cover its drug products could have a material adverse effect on the manufacturer's sales, results of operations and financial condition.

General legislative cost control measures may also affect reimbursement for drug products. Manufacturers that obtain approval to market a drug candidate in the United States may be subject to spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs and/or any significant taxes or fees.

Government Regulation

Government authorities in the United States, at the federal, state and local level, and in other countries and jurisdictions extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, marketing, post-approval monitoring and reporting, and import and export of pharmaceutical products. The processes for obtaining regulatory approvals in the United States and in foreign countries and jurisdictions, along with subsequent compliance with applicable statutes and regulations and other regulatory authorities, require the expenditure of substantial time and financial resources.

U.S. Drug and Biologic Development Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA under the Federal Food, Drug, and Cosmetic Act ("FDCA") and its implementing regulations. Biologics are additionally subject to the Public Health Service Act and its implementing regulations. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies in accordance with Good Laboratory Practice regulations ("GLPs") and other applicable regulations;

- submission to the FDA of an Investigational New Drug ("IND") application, which must become effective before human clinical trials may begin;

- approval by an independent institutional review board ("IRB") or ethics committee at each clinical site before each trial may be initiated;

- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practice regulations ("GCPs") to evaluate the safety and efficacy of the drug for its intended use;

- submission to the FDA of an NDA or Biologics License Application ("BLA");

- a determination by the FDA within 60 days of its receipt of the NDA or BLA to file the submission for review;

- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the product is produced to assess compliance with current Good Manufacturing Practice ("cGMP") requirements to assure that the facilities, methods and controls are adequate to preserve its identity, strength, quality and purity, and of inspection of selected clinical investigation sites to assess compliance with GCPs; and

- FDA review and approval of the NDA or BLA to permit commercial marketing of the product for particular indications for use in the United States.

Nonclinical tests include laboratory evaluation of product chemistry, formulation and toxicity, as well as animal trials to assess the characteristics and potential safety and efficacy of the product. The conduct of the nonclinical tests must comply with federal regulations and requirements, including GLPs, where applicable. The results of nonclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls ("CMC"), and a proposed clinical trial protocol. Long-term preclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted. An IND automatically becomes effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions related to one or more proposed clinical trials and places the trial on clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin.

Clinical trials involve the administration of the investigational product to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations; (ii) in compliance with GCPs, which are standards meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators and monitors; as well as (iii) under protocols detailing the objectives of the trial, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time, or impose other sanctions, if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The study protocol and informed consent information for patients in clinical trials must also be submitted to an IRB for approval before a clinical trial commences at the relevant institution. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB's requirements, or may impose other conditions on the conduct of the study.

Human clinical trials are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the investigational product into healthy subjects or patients, safety, dosage tolerance, metabolism, pharmacokinetics, pharmacological actions, side effects and, if possible, to early evidence on effectiveness are assessed. Phase 2 usually involves trials in a limited patient population with the specified disease or conditions to evaluate the effectiveness of the investigational product for a particular indication, to determine optimal dose and regimen, and to identify common AEs and safety risks. If preliminary evidence of effectiveness and an acceptable safety profile is obtained in Phase 2 evaluations, Phase 3 trials are conducted. Phase 3 trials are undertaken to obtain additional information about clinical efficacy and safety in an expanded patient population, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the investigational product and to provide adequate information for labeling.

In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the safety and efficacy of a product. A single Phase 3 trial may be sufficient (1) where the study is a large, multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity or prevention of a disease with a potentially serious outcome and confirmation of the result in a second trial would be practically or ethically impossible or (2) when the single trial is supported by confirmatory evidence.

Post-approval trials, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval. These

trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA or BLA.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the chemistry and physical characteristics of the product and finalize a process for manufacturing the product in commercial quantities in accordance with cGMPs. The manufacturing process must be capable of consistently producing quality batches and, among other things, the manufacturer must develop methods for testing the identity, strength, quality and purity of the finished product. In addition, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product does not undergo unacceptable deterioration over its shelf life.

U.S. Review and Approval Process

After completion of the required clinical testing, the sponsor prepares and submits an NDA or BLA to the FDA. FDA approval of the application is required before marketing and distribution of the product may begin in the United States. The application must include, among other information, the results of all nonclinical, clinical, and other testing along with descriptions of the manufacturing process, analytical tests conducted on the product, and proposed labeling. The cost of preparing and submitting an application is substantial. The submission of most applications is additionally subject to a substantial user fee. Under an approved NDA or BLA, the applicant is also subject to an annual program fee. These fees are typically increased annually.

The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be filed based on the FDA's threshold determination that it is sufficiently complete to permit substantive review. Once the submission is filed, the FDA begins an in-depth review. Under the Prescription Drug User Fee Act, as amended ("PDUFA"), the FDA has agreed to certain performance goals. The FDA's goal is to review and act on applications granted Standard Review within ten months of the date the FDA files the application. For applications granted a Priority Review, the FDA's goal is to review the application within six months from the date the FDA files the application. The FDA may extend its PDUFA goal date for reviewing both standard and priority-review applications for three additional months to allow the FDA to consider certain late-submitted information or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel products, as well as those that present difficult questions of safety or efficacy, to an advisory committee—typically a panel that includes clinicians and other experts—for review, evaluation and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations.

Before approving an NDA or BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will generally inspect the facility or the facilities at which the product is manufactured. The FDA will not approve a product unless the facility at which it is manufactured has a satisfactory cGMP compliance status.

After the FDA evaluates the NDA or BLA and completes any clinical and manufacturing site inspections, it issues either an approval letter or a complete response letter. An approval letter authorizes commercial marketing of the product with prescribing information for specific indications. A complete response letter indicates that the review cycle of the application is complete, and the application will not be approved in its present form. A complete response letter generally outlines the deficiencies in the application and may require substantial additional testing or information that must be provided in order for the FDA to reconsider the application for approval. If, or when, those deficiencies have been addressed to the FDA's satisfaction in a resubmission of the application, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months from the date of receipt, depending on the type of information included.

As a condition of approval, the FDA may require a risk evaluation and mitigation strategy ("REMS") to help ensure that the benefits of the product outweigh the potential risks. REMS can include medication guides, communication plans for healthcare professionals, and elements to assure safe use ("ETASU"). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring,

and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the product. Moreover, the FDA may require substantial post-approval testing and surveillance to monitor the product's safety or efficacy.

FDA Expedited Development and Review Programs

The FDA has a number of programs intended to expedite the development or review of a marketing application for an investigational product. For example, the Fast Track designation program is intended to expedite or facilitate the process for developing and reviewing drug products that meet certain criteria. Specifically, investigational drugs and biologics are eligible for Fast Track designation if they are intended to treat a serious or life-threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. The sponsor of a Fast Track designated investigational product has opportunities for more frequent interactions with the applicable FDA review team during product development and, once an NDA or BLA is submitted, the application may be eligible for priority review. The FDA may consider for review sections of the NDA or BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

A drug biologic intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation to expedite its development and review. Breakthrough Therapy designation is provided if preliminary clinical evidence indicates that the drug or biologic, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. The designation includes all of the Fast Track program features, as well as more intensive FDA interaction and guidance beginning as early as Phase 1 and an organizational commitment to expedite the development and review of the product, including involvement of senior managers.

Any drug or biologic product submitted to the FDA for approval may also be eligible for Priority Review. An NDA or BLA is eligible for Priority Review if the product is designed to treat a serious condition, and if approved, would provide a significant improvement in safety or efficacy compared to available therapies. The FDA will attempt to direct additional resources to the evaluation of an application designated for priority review.

Fast Track designation, Breakthrough Therapy designation, and Priority Review do not change the standards for approval but may expedite the development or approval process. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decide that the time period for FDA review or approval will not be shortened.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of FDA-regulated products, including investigational drugs, are required to register and disclose certain clinical trial information on ClinicalTrials.gov. Information related to the product, patient population, phase of investigation, study sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Pediatric Information

Under the Pediatric Research Equity Act, NDAs, BLAs or supplements thereto must contain data to assess the safety and effectiveness of the product for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is determined by the FDA to be safe and effective. The FDA may grant full or partial waivers or deferrals for submission of data. A deferral may be granted for several reasons, including a finding that the product is ready for approval for use in adults before pediatric clinical trials are complete or that additional safety or effectiveness data needs to be collected before the pediatric clinical trials begin. The

FDA must send a non-compliance letter to any sponsor that fails to submit the required assessment, keep a deferral current or submit a request for approval of a pediatric formulation.

The Best Pharmaceuticals for Children Act ("BPCA") provides NDA and BLA holders a six-month extension of any exclusivity—patent or nonpatent—for a product if certain conditions are met. Conditions for exclusivity include the FDA's determination that information relating to the use of the product in the pediatric population may produce health benefits in that population, the FDA making a "written request" for pediatric studies, and the applicant agreeing to perform, and reporting on, the requested studies within the statutory timeframe. Applications or supplements to an approved application that propose a labeling change as a result of pediatric studies conducted pursuant to the BPCA are treated as priority applications or supplements, with all of the benefits that designation confers.

Post-Approval Requirements

Any products manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to record-keeping, reporting of adverse experiences, periodic reporting, product sampling and distribution, and advertising and promotion of the product. After approval, many changes to the approved product, such as adding new indications, certain manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

Drug and biologic manufacturers and certain of their subcontractors are required to register their establishments with the FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the FDA inspects manufacturing facilities to assess compliance with cGMP. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMP.

The FDA may withdraw 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, including AEs of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of requirements for post-market studies or clinical studies to assess new safety risks; or imposition of distribution restrictions or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- warning or untitled letters;
- clinical holds on clinical studies;
- refusal of the FDA to approve pending applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs;
- mandated modification of promotional materials and labeling and the issuance of corrective information;
- the issuance of safety alerts, Dear Healthcare Provider letters, press releases and other communications containing warnings or other safety information about the product; or
- injunctions, fines or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of drugs and biologics that are placed on the market. Advertising and promotion of drugs and biologics must be in compliance with the FDCA and its implementing regulations and only for the approved indications and in a manner consistent with the 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, including investigation by federal and state authorities.

Foreign Drug Development Processes

In addition to regulations in the United States, we are and will continue to be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials, authorization, and any commercial sales and distribution of our products. Whether or not we obtain FDA approval of a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. Many countries outside of the United States have a process similar to that in the United States that requires the submission of a clinical trial application ("CTA") much like the IND prior to the commencement of human clinical trials.

Although in countries outside of the EU, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country in all cases, the clinical trials must be conducted in accordance with GCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

If we or our potential collaborators fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension, variation or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Clinical Trials in the EU

Similarly to the United States, the various phases of non-clinical and clinical research in the EU are subject to significant regulatory controls.

In the EU, clinical trials are governed by the Clinical Trials Regulation (EU) No 536/2014 (the "CTR"), which entered into application on January 31, 2022, repealing and replacing the former Clinical Trials Directive 2001/20 (the "CTD").

The CTR is intended to harmonize and streamline CTA, simplify adverse-event reporting procedures, improve the supervision of clinical trials and increase transparency. Specifically, the regulation, which is directly applicable in all EU member states, introduces a streamlined application procedure through a single-entry point, the "EU portal"; the Clinical Trials Information System ("CTIS"); a single set of documents to be prepared and submitted for the application; as well as simplified reporting procedures for clinical trial sponsors. A harmonized procedure for the assessment of applications for clinical trials has been introduced and is divided into two parts. Part I assessment is led by the competent authorities of a reference member state selected by the trial sponsor and relates to clinical trial aspects that are considered to be scientifically harmonized across EU member states. This assessment is then submitted to the competent authorities of all concerned member states in which the trial is to be conducted for their review. Part II is assessed separately by the competent authorities and ethics committees in each concerned EU member state, i.e., all EU member states in which a clinical trial is to be conducted. Individual EU member states retain the power to authorize the conduct of clinical trials on their territory.

The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

Medicinal products used in clinical trials must be manufactured in accordance with the guidelines on GMP and in a GMP certified facility, which is subject to GMP inspections.

Review and Approval Process of Medicinal Products in the EU

In the EU, medicinal products can only be commercialized after a related marketing authorization ("MA") has been granted. To obtain an MA for a medicinal product in the EU, an applicant must submit a Marketing Authorization Application ("MAA"), either in accordance with a centralized procedure administered by the EMA, or one of the procedures administered by the competent authorities of EU member states (decentralized procedure, national procedure or mutual recognition procedure). An MA may be granted only to an applicant established in the EU.

A successful application in accordance with the centralized procedure results in the grant of a single MA by the European Commission that is valid throughout the EU. Pursuant to Regulation (EC) No 726/2004, the centralized procedure is compulsory for specific products, including for (i) medicinal products derived from biotechnological processes, (ii) products designated as orphan medicinal products, (iii) advanced therapy medicinal products ("ATMPs"), and (iv) products with a new active substance indicated for the treatment of HIV/AIDS, cancer, neurodegenerative diseases, diabetes, auto-immune and other immune dysfunctions and viral diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, authorization through the centralized procedure is optional on related approval.

In accordance with the centralized procedure, the EMA's Committee for Medicinal Products for Human Use (the "CHMP"), conducts the initial assessment of an application for authorization of a medicinal product. The CHMP is also responsible for several post-authorization and maintenance activities, such as the assessment of variations or extensions to an existing MA. The maximum timeframe for the evaluation of an MAA under the centralized procedure is 210 days, excluding clock stops during which additional information or written or oral explanations are provided by the applicant in response to questions of the CHMP. Accelerated assessment may be granted by the CHMP in exceptional cases, when a medicinal product that targets an unmet medical need is expected to be of major interest from the point of view of public health and, in particular, from the viewpoint of therapeutic innovation. If the CHMP accepts a request for accelerated assessment, the time limit of 210 days will be reduced to 150 days (excluding clock stops). The CHMP can, however, revert to the standard time limit for the centralized procedure if it considers that it is no longer appropriate to conduct an accelerated assessment.

Unlike the centralized authorization procedure, the decentralized MA procedure requires a separate application to, and leads to separate approval by, the competent authorities of each EU member state in which the product is to be marketed. This application is identical to the application that would be submitted to the EMA for authorization through the centralized procedure. The reference EU member state prepares a draft assessment and drafts of the related materials within 120 days after receipt of a valid MAA. The resulting assessment report is submitted to the concerned EU member states who, within 90 days of receipt, must decide whether to approve the assessment report and related materials. If a concerned EU member state cannot approve the assessment report and related materials due to concerns relating to a potential serious risk to public health, disputed elements may be referred to the Heads of Medicines Agencies' Coordination Group for Mutual Recognition and Decentralized Procedures — Human ("CMDh") for review. The subsequent decision of the European Commission is binding on all EU member states.

The mutual recognition procedure allows companies that have a medicinal product already authorized in one EU member state to apply for this authorization to be recognized by the competent authorities in other EU member states. Like the decentralized procedure, the mutual recognition procedure is based on the acceptance by the competent authorities of the EU member states of the MA granted in relation to a medicinal product by the competent authorities of other EU member states. The holder of a national MA may submit an application to the competent authority of an EU member state requesting that this authority recognize the MA delivered by the competent authority of another EU member state.

An MA has, in principle, an initial validity of five years. The MA may be renewed after five years on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the EU member state in which the original MA was granted. To support the application, the MA holder must provide the EMA or the competent authority with a consolidated version of the Common Technical Document providing up-to-date data concerning the quality, safety and efficacy of the product, including all variations introduced since the MA was granted, at least nine months before the MA ceases to be valid. The European Commission or the competent authorities of the EU member states may decide on justified grounds relating to pharmacovigilance, to proceed with one further five-year renewal period for the MA. Once subsequently definitively renewed, the MA shall be valid for an unlimited period. Any authorization which is not followed by the actual placing of the medicinal product on the EU market (for a centralized MA) or on the market of the authorizing

EU member state within three years after authorization ceases to be valid (the so-called sunset clause) unless, in justified circumstances, authorization is extended.

Innovative products that target an unmet medical need and are expected to be of major public health interest may be eligible for a number of expedited development and review programs, such as the PRIority MEdicines ("PRIME") scheme, which provides incentives similar to the breakthrough therapy designation in the U.S. PRIME is a voluntary scheme aimed at enhancing the EMA's support for the development of medicinal products that target unmet medical needs. Eligible products must target conditions for which there is an unmet medical need; i.e., where there is no satisfactory method of diagnosis, prevention or treatment in the EU or, if there is, the new medicinal product will bring a major therapeutic advantage. The products must demonstrate the potential to address the unmet medical need by introducing new methods of therapy or improving existing ones. Benefits accrue to sponsors of product candidates with PRIME designation, including but not limited to, early and proactive regulatory dialogue with the EMA, frequent discussions on clinical trial designs and other development program elements, and potentially accelerated MAA assessment once a dossier has been submitted.

In the EU, a "conditional" MA may be granted in cases where all the required safety and efficacy data are not yet available. The European Commission may grant a conditional MA for a medicinal product if it is demonstrated that all of the following criteria are met: (i) the benefit-risk balance of the medicinal product is positive; (ii) it is likely that the applicant will be able to provide comprehensive data post-authorization; (iii) the medicinal product fulfils an unmet medical need; and (iv) the benefit of the immediate availability to patients of the medicinal product is greater than the risk inherent in the fact that additional data are still required. The conditional MA is subject to conditions to be fulfilled for generating the missing data or ensuring increased safety measures. It is valid for one year and must be renewed annually until all related conditions have been fulfilled. Once any pending studies are provided, the conditional MA can be converted into a standard MA. However, if the conditions are not fulfilled within the timeframe set by the EMA and approved by the European Commission, the MA will cease to be renewed.

An MA may also be granted "under exceptional circumstances" where the applicant can show that it is unable to provide comprehensive data on efficacy and safety under normal conditions of use even after the product has been authorized and subject to specific procedures being introduced. These circumstances may arise in particular when the intended indications are very rare and, in the state of scientific knowledge at that time, it is not possible to provide comprehensive information, or when generating data may be contrary to generally accepted ethical principles. Like a conditional MA, an MA granted in exceptional circumstances is reserved to medicinal products intended to be authorized for treatment of rare diseases or unmet medical needs for which the applicant does not hold a complete data set that is required for the grant of a standard MA. However, unlike the conditional MA, an applicant for authorization in exceptional circumstances is not subsequently required to provide the missing data. Although the MA "under exceptional circumstances" is granted definitively, the risk-benefit balance of the medicinal product is reviewed annually, and the MA will be withdrawn if the risk-benefit ratio is no longer favorable.

Pediatric Development in the EU

In the EU, Regulation (EC) No 1901/2006 provides that all MAAs for new medicinal products must include the results of trials conducted in the pediatric population, in compliance with a pediatric investigation plan ("PIP") agreed with the EMA's Pediatric Committee ("PDCO"). The PIP sets out the timing and measures proposed to generate data to support a pediatric indication of the medicinal product for which MA is being sought. The PDCO can grant a deferral of the obligation to implement some or all of the measures provided in the PIP until there are sufficient data to demonstrate the efficacy and safety of the product in adults. Further, the obligation to provide pediatric clinical trial data can be waived by the PDCO when these data are not needed or appropriate because the product is likely to be ineffective or unsafe in children, the disease or condition for which the product is intended occurs only in adult populations, or when the product does not represent a significant therapeutic benefit over existing treatments for pediatric patients. Once the MA is obtained in all EU member states and study results are included in the product information, even when negative, the product is eligible for a six-month extension to the Supplementary Protection Certificate ("SPC"), if any is in effect at the time of authorization or, in the case of orphan medicinal products, a two-year extension of orphan market exclusivity.

Data and Market Exclusivity in the EU

The EU provides opportunities for data and market exclusivity related to MAs. Upon receipt of an MA, innovative medicinal products (i.e., reference products) are generally entitled to benefit from eight years of data exclusivity and an additional two years of market exclusivity. Data exclusivity, if granted, prevents generic and biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar MA in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial MA of the reference product in the EU. The overall ten-year period may, occasionally, be extended for a further year to a maximum of 11 years if, during the first eight years of those ten years, the MA holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies. However, there is no guarantee that a product will be considered by the EU's regulatory authorities to be a new chemical/biological entity, and products may not qualify for data exclusivity.

In the EU, there is a special regime for biosimilars, or biological medicinal products that are similar to a reference medicinal product but that do not meet the definition of a generic medicinal product. For such products, the results of appropriate preclinical or clinical trials must be provided in support of an application for MA. Guidelines from the EMA detail the type of quantity of supplementary data to be provided for different types of biological product.

Manufacturing Regulation in the EU

In addition to an MA, various other requirements apply to the manufacture and placing on the EU market of medicinal products. The manufacture of medicinal products in the EU requires a manufacturing authorization. Moreover, import of medicinal products into the EU requires a manufacturing authorization allowing for import. The holder of a manufacturing authorization must comply with various requirements set out in the applicable EU laws, regulations and guidance, including GMP standards. Similarly, the distribution of medicinal products within the EU is subject to compliance with applicable EU laws, regulations and guidelines, including the requirement to hold appropriate authorizations for distribution granted by the competent authorities of EU member states. MA holders and/or manufacturing and import authorization, or MA holders and/or distribution authorization holders may be subject to civil, criminal or administrative sanctions, including suspension of manufacturing authorization, in case of non-compliance with the EU or EU member states' requirements applicable to the manufacturing of medicinal products.

Post-authorization Requirements in the EU

Where an MA is granted in relation to a medicinal product in the EU, the holder of the MA is required to comply with a range of regulatory requirements applicable to the manufacture, marketing, promotion and sale of medicinal products. Similar to the United States, both MA holders and manufacturers of medicinal products are subject to comprehensive regulatory oversight by the EMA, the European Commission and/or the competent regulatory authorities of the individual EU member states. The holder of an MA must establish and maintain a pharmacovigilance system and appoint an individual qualified person for pharmacovigilance who is responsible for oversight of that system. Key obligations include expedited reporting of suspected serious adverse reactions and submission of periodic safety update reports ("PSURs").

All new MAAs must include a risk management plan ("RMP"), describing the risk management system that the company will put in place and documenting measures to prevent or minimize the risks associated with the product. The regulatory authorities may also impose specific obligations as a condition of the MA. Such risk minimization measures or post-authorization obligations may include additional safety monitoring, more frequent submission of PSURs, or the conduct of additional clinical trials or post-authorization safety studies.

In the EU, the advertising and promotion of medicinal products are subject to both EU and EU member states' laws governing promotion of medicinal products, interactions with physicians and other healthcare professionals, misleading and comparative advertising and unfair commercial practices. General requirements for advertising and promotion of medicinal products, such as direct-to-consumer advertising of prescription medicinal products are established in EU law. However, the details are governed by regulations in individual EU member states and can differ from one country to another. For example, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC"), which may require approval by the competent

national authorities in connection with an MA. The SmPC is the document that provides information to physicians and other healthcare professionals concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU.

The aforementioned EU rules are generally applicable in the European Economic Area (which is comprised of the 27 EU member states plus Norway, Iceland and Liechtenstein).

Failure to comply with EU and member state laws that apply to the conduct of clinical trials, manufacturing approval, MA of medicinal products and marketing of such products, both before and after grant of the MA, manufacturing of pharmaceutical products, statutory health insurance, bribery and anti-corruption or with other applicable regulatory requirements may result in administrative, civil or criminal penalties. These penalties could include delays or refusal to authorize the conduct of clinical trials, or to grant MA, product withdrawals and recalls, product seizures, suspension, withdrawal or variation of the MA, total or partial suspension of production, distribution, manufacturing or clinical trials, operating restrictions, injunctions, suspension of licenses, fines and criminal penalties.

Pricing, Coverage and Reimbursement in the EU

In the EU, pricing and reimbursement schemes vary widely from country to country. Some EU member states may approve a specific price for a product, or they may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. Other EU member states allow companies to fix their own prices for products but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions.

In addition, some EU member states may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This Health Technology Assessment ("HTA"), process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states.

On January 12, 2025, Regulation No 2021/2282 on Health Technology Assessment (the "HTA Regulation") entered into application through a phase implementation. The Regulation initially applies to new active substances for oncology and ATMPs. It will be expanded to orphan medicinal products in January 2028, and to all centrally authorized medicinal products as of 2030. Select high-risk medical devices also came into scope in 2026. The Regulation is intended to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and establishes the framework for EU level joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. The HTA Regulation is intended to harmonize the clinical benefit assessment of HTA across the EU. The Regulation permits EU Member States to use common tools, methodologies, and procedures and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU Member States will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

UK Regulation

The Medicines and Healthcare products Regulatory Agency ("MHRA") is the United Kingdom's standalone regulator for medicinal products and medical devices.

While the UK regulatory framework in relation to clinical trials was historically based on the Medicines for Human Use (Clinical Trials) Regulations 2004, which implemented the former EU Clinical Trials Directive, this has been significantly reformed by the Medicines for Human Use (Clinical Trials) (Amendment) Regulations 2024. The new legislation, which was adopted in April 2025, modernizes the United Kingdom's approach to make it a more attractive location for research, and includes key features such as: (i) a risk-proportionate approach, including a notification scheme for lower-risk trials; (ii) a combined review process integrating ethics committee and regulatory approvals into a single, streamlined pathway; (iii) enhanced transparency requirements mandating registration of clinical trials in a public registry and publication of trial results within 12 months of trial completion (with scope for deferrals in certain circumstances); (iv) greater flexibility

to support innovation in clinical trial design; and (v) measures to promote patient and public involvement. The amendments will become applicable on April 28, 2026 following a one-year transition period.

Marketing authorizations in the UK are governed by the Human Medicines Regulations (SI 2012/1916), as amended. To obtain a UK MA to commercialize products in the UK, an applicant must be established in the UK and must follow one of the UK national authorization procedures or one of the remaining post-Brexit international cooperation procedures. Applications are governed by the Human Medicines Regulations (SI 2012/1916) and are made electronically through the MHRA Submissions Portal. The MHRA has introduced changes to national licensing procedures, including procedures to prioritize access to new medicines that will benefit patients, a 150-day assessment (subject to clock-stops) and a rolling review procedure. The rolling-review procedure permits the separate or joint submission of quality, non-clinical, and clinical data to the MHRA which can be reviewed on a rolling basis. After an application under the rolling-review procedure has been validated, the decision should be received within 100 days (subject to clock-stops).

In addition, since January 1, 2024, the MHRA may rely on the International Recognition Procedure ("IRP"), when reviewing certain types of MAAs. Pursuant to the IRP, the MHRA will take into account the expertise and decision-making of trusted regulatory partners (e.g., the regulatory in Australia, Canada, Switzerland, Singapore, Japan, the United States and the EU). The MHRA will conduct a targeted assessment of IRP applications but retain the authority to reject applications if the evidence provided is considered insufficiently robust. The IRP allows medicinal products approved by such trusted regulatory partners that meet certain criteria to undergo a fast-tracked MHRA review to obtain and/or update a MA in the UK. Applications should be decided within a maximum of 60 days if there are no major objections identified that cannot be resolved within such 60-day period and the approval from the trusted regulatory partner selected has been granted within the previous two years or if there are such major objections identified or such approval hasn't been granted within the previous two years within 110 days. Applicants can submit initial MAAs to the IRP, but the procedure can also be used throughout the lifecycle of a product for post-authorization procedures including line extensions, variations and renewals.

Japanese Regulation

Manufacturers and sellers of drugs, quasi-drugs, cosmetics, medical devices and regenerative medical products ("Designated Products") in Japan are subject to the supervision of Japan's Ministry of Health, Labour and Welfare ("MHLW") primarily under the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics of Japan ("PMDA" or "PMD Act"). Under the PMD Act, the relevant licenses must be obtained from the MHLW in order to conduct the business of manufacturing, marketing or selling Designated Products.

Applications for the approval of new products are made through the PMDA. The clinical trial data and other pertinent data must be attached to the application for approval. If the drugs, medical devices or regenerative medical products under application are of types designated by ministerial ordinance of the MHLW, the attached data mentioned above must be obtained in compliance with the standards established by the minister of the MHLW ("Minister"), such as the Good Laboratory Practice and the Good Clinical Practice. Once an application for approval is submitted, a review team is formed, which consists of specialized officials of the PMDA, including experts on chemistry/manufacturing, non-clinical, clinical, and biostatistics. Team evaluation results are passed to the PMDA's external experts, who then report back to the PMDA. After a further team evaluation, a report is provided to the Minister; the Minister makes a final determination for approval and refers this to the Council on Drugs and Foods Sanitation, which then advises the MHLW on final approvability. Marketing and distribution approvals require a review to determine whether or not the product in the application is suitable as a drug to be manufactured and distributed with which a manufacturing and distribution business license for the type of drug concerned has been obtained, and to confirm that the product has been manufactured in a plant compliant with the GMP.

Once the MHLW has approved the application, the company can make the new drug available for physicians to prescribe. After that, the MHLW lists its National Health Insurance price within 60 days (or 90 days at the latest) from the approval, and physicians can obtain reimbursement. For some medications, the MHLW requires additional post marketing studies (Phase 4) to further evaluate safety and/or to gather information concerning the quality, efficacy, and safety of the product under specified conditions, in addition to post marketing surveillance including Early Post-marketing Phase Vigilance

("EPPV") based on the RMP for all new medications. The MHLW also requires the drug's sponsor to submit periodic safety update reports. Within three months from the specified re-examination period, which is designated at the time of the approval of the application for the new product, the company must submit a re-examination application to enable the drug's quality, efficacy, and safety to be reassessed against approved labeling by the PMDA.

The PMD Act also provides for special regulations applicable to drugs, quasi-drugs, cosmetics and medical devices made of biological raw materials. These regulations impose various obligations on manufacturers and other persons in relation to manufacturing facilities, explanation to patients, labeling on products, record-keeping and reporting to the Minister.

Under the PMD Act, the Minister may take various measures to supervise manufacturing and marketing license holders of Designated Products. The Minister has the authority to order manufacturing and marketing license holders to temporarily suspend the marketing, leasing or providing of the Designated Products to prevent risks or increases in risks to the public health. Also, the Minister may revoke a license or approval granted to a manufacturing and marketing license holder or order a temporary business suspension under certain limited circumstances such as violation of laws relating to drugs.

The Hatch-Waxman Amendments

Orange Book Listing

Under the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the Hatch Waxman Amendments, NDA applicants are required to identify to FDA each patent whose claims cover the applicant's drug or approved method of using the drug. Upon approval of a drug, the applicant must update its listing of patents to the NDA in timely fashion and 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 generic competitors in support of approval of an abbreviated new drug application ("ANDA"). An ANDA provides for marketing of a drug product that has the same active ingredient(s), strength, route of administration and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. An approved ANDA product is considered to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, preclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved under the ANDA pathway 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 pursuant to each state's laws on drug substitution.

The ANDA applicant is required to certify to the FDA concerning any patents identified for the reference listed drug in the Orange Book. Specifically, the applicant must certify to each patent in one of the following ways: (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. 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. For patents listed that claim an approved method of use, under certain circumstances the ANDA applicant may also elect to submit a section viii statement certifying that its proposed ANDA label does not contain (or carves out) any language regarding the patented method-of-use rather than certify to a listed method-of-use patent. If the applicant does not challenge the listed patents through a Paragraph IV certification, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA-holder and patentee(s) once the ANDA has been received by the FDA for review (referred to as the "notice letter"). The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice letter. 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 until the earlier of 30 months from the date the notice letter is received, expiration of the patent, the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the subject of the certification is invalid or not infringed, or a decision in the patent case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired. In some instances, an ANDA applicant may receive approval prior to expiration of certain non-patent exclusivity if the applicant seeks, and FDA permits, the omission of such exclusivity-protected information from the ANDA prescribing information.

Hatch-Waxman Exclusivity

Market exclusivity provisions under the FDCA can delay the submission or the approval of certain marketing applications. For example, upon NDA approval of a new chemical entity ("NCE"), which is a drug that contains no active moiety that has been approved by FDA in any other NDA, that drug receives five years of non-patent data exclusivity during which FDA cannot receive (1) any ANDA seeking approval of a generic version of that drug or (2) an NDA submitted under Section 505(b)(2) of the FDCA (505(b)(2) NDA) by another company for another drug based on the same active moiety, regardless of whether the drug is intended for the same indication as the original innovative drug or for another indication. However, an ANDA or a 505(b)(2) NDA 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 (i.e., a Paragraph IV certification).

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 or strengths of an existing drug. This three-year exclusivity covers only the modification for which the drug received approval on the basis of the new clinical investigations and does not prohibit the FDA from approving ANDAs or 505(b)(2) NDAs for drugs containing the active moiety for any other indication or condition of use. Five-year and three-year exclusivity will not delay the submission or approval of a full NDA. However, an applicant submitting a full NDA would be required to conduct, or obtain a right of reference to, all of the nonclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

The Hatch Waxman Amendments permit a patent term extension as compensation for patent term lost during the FDA regulatory review process. Patent term extension, however, cannot extend the remaining term of a patent beyond a total of 14 years from the product's approval date. After NDA approval, owners of relevant drug patents may apply for the extension. The allowable patent term extension is calculated as half of the drug's testing phase (the time between IND application and NDA submission) and all of the review phase (the time between NDA submission and approval) up to a maximum of five years. The time can be reduced for any time FDA determines that the applicant did not pursue approval with due diligence.

The United States Patent and Trademark Office ("USPTO") in consultation with the FDA, reviews and approves the application for any patent term extension or restoration. However, the USPTO may not grant an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, 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 requested.

The total patent term after the extension may not exceed 14 years, and only one patent can be extended. The application for the extension must be submitted prior to the expiration of the patent, and for patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other U.S. Regulatory Matters

Manufacturing, sales, promotion and other activities following drug approval are also subject to regulation by numerous

regulatory authorities in addition to the FDA, including, in the United States, the Centers for Medicare & Medicaid Services ("CMS"), other divisions of HHS, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

The failure to comply with regulatory requirements subjects manufacturers to possible legal or regulatory action.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. For example, the federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, impose privacy, security and breach notification obligations on certain health care providers, health plans, and health care clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities. Entities that are found to be in violation of HIPAA may be subject to significant civil, criminal and administrative fines and penalties, and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. Further, entities that knowingly obtain, use, or disclose individually identifiable health information maintained by a HIPAA covered entity in a manner that is not authorized or permitted by HIPAA may be subject to criminal penalties. In addition, certain state laws govern the privacy and security of personal information, including health-related information, in certain circumstances. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, the California Consumer Privacy Act ("CCPA") imposes certain data privacy obligations for covered companies and provides certain privacy rights to California residents. Other states have also enacted, proposed, or are considering proposing, data privacy laws. In addition, certain foreign laws govern the privacy and security of personal information, including health-related information. Privacy and security laws, regulations, and other obligations are constantly evolving, may conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Other U.S. Healthcare Laws

Pharmaceutical manufacturers are subject to numerous federal and state laws and regulations including, without limitation, state and federal anti-kickback, fraud and abuse, false claims and transparency laws, such as the following:

- federal Anti-Kickback Statute, which prohibit, among other things, persons from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- federal false claims laws, including the False Claim Act and the Civil Monetary Penalties Law, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, information or claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent. In addition, a claim including items or services resulting from a violation of the U.S. federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act;

- HIPAA, which, in addition to the privacy, security, and breach notification obligations described above, also prohibits, among other things, executing or attempting to execute a scheme to defraud any healthcare benefit program (including private health plans) or making false statements relating to healthcare 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 in order to have committed a violation;

- the FDCA, which among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products prior to approval or for off-label use and regulates the distribution of samples;

- federal laws that require pharmaceutical manufacturers to report certain calculated product prices to the government or provide certain discounts or rebates to government authorities or private entities, often as a condition of reimbursement under government healthcare programs;

- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), other healthcare professionals (such as physician assistants and nurse practitioners) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- state law equivalents of the above federal laws, such as anti-kickback and false claims laws, which may apply to items or services reimbursed by any third-party payer, including private insurers, state transparency laws, and state laws limiting interactions between pharmaceutical manufacturers and members of the healthcare industry, many of which differ from each other in significant ways and may not have the same effect, and often are not preempted by HIPAA.

Violations of such laws may result in significant penalties, including criminal, civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, integrity oversight and reporting obligations, diminished profits and future earnings, and the curtailment or restructuring of operations.

U.S. Healthcare Reform

The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price-controls, restrictions on reimbursement, and requirements for substitution of generic products for branded prescription drugs. For example, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act (collectively, the "ACA") was passed which substantially changed the way healthcare is financed by both the government and private insurers and continues to significantly impact the U.S. pharmaceutical industry. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the One Big Beautiful Bill Act (the "OBBBA") was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA 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 ACA 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 or additional pricing pressures.

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 establishing Most-Favored-Nation pricing for pharmaceutical products and launching an online clearinghouse, referred to as TrumpRx, for patients to purchase certain products from manufacturers on a cash pay basis; (3) ongoing trade tensions between the United States and other jurisdictions that have resulted in multiple rounds of tariffs and potential tariffs affecting 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, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could, among other things, impact the drug approval process and make changes to the Medicare Drug Price Negotiation Program.

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical 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.

Employees and Human Capital Resources

As of December 31, 2025, we employed 221 full-time and 3 part-time employees, consisting of clinical, scientific, development, regulatory, finance, legal and operational personnel. We also retain independent contractors to support certain organizational needs. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

We recognize that our culture is central to the productivity, agility, scalability and competitiveness of our operation, and is essential to our success. We are clear and consistent in our company values and we communicate and support an employee value proposition. Our proposition is centered with unique and impactful professional development opportunities within an environment of inclusive representation and diverse thinking as a unifying force and business differentiator. Our employees are critical to our long-term success and are essential to helping us meet our goals. Among other things, we support and incentivize our employees in the following ways:

- *Talent development, compensation and retention:* Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and additional employees. The principal purposes of our equity incentive plans are to attract, retain and motivate selected employees, consultants and directors through the granting of stock-based compensation awards.

- *Health and safety:* We support the health and safety of our employees by providing comprehensive insurance benefits, an employee assistance program, company-paid holidays, a personal time-off program and other additional benefits which are intended to assist employees to manage their well-being.

- *Inclusion and diversity workplace:* We are committed to an inclusive and diverse workplace because we believe that fostering an inclusive work environment with a team of employees having wide-ranging backgrounds, experiences, perspectives and skillsets enhances our corporate culture and is key to our long-term success.

Item 1A. Risk Factors

Investing in our common stock involves a high degree of risk. Before deciding to invest in shares of our common stock, you should carefully consider the risks described below, together with the other information contained in this Annual Report on Form 10-K, including in the section titled "Management's Discussion and Analysis of Financial Condition and

Results of Operations" and in our audited consolidated financial statements and the related notes included elsewhere in this Annual Report on Form 10-K. We cannot assure you that any of the events discussed below will not occur. These events could adversely impact our business, financial condition, results of operations and prospects. If that were to happen, the trading price of our common stock could decline, and you could lose all or part of your investment.

Risks Related to Our Financial Position and Need for Capital

We are a clinical stage biopharmaceutical company with a limited operating history and no products approved for commercial sale, and have incurred substantial losses since our inception and anticipate incurring substantial and increasing losses for the foreseeable future.

We are a clinical stage biopharmaceutical company with a limited operating history on which to base your investment decision. We have no product candidates approved for commercial sale and have not generated any revenue. Biopharmaceutical product development is a highly speculative undertaking. It entails substantial upfront capital expenditures and significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval or become commercially viable.

Our most advanced candidate is envu, an oral, small molecule allosteric inhibitor of TYK2. We are currently conducting a Phase 2 open-label extension trial, as well as a Phase 3 LTE trial of envu in PsO and a Phase 2b clinical trial of envu in SLE. In addition, we are advancing A-005, an investigational CNS penetrant allosteric inhibitor of TYK2 that has a potential application in multiple sclerosis and other neuroinflammatory and neurodegenerative diseases, currently in Phase 1 clinical development. Our ability to achieve profitability in the future is dependent upon obtaining regulatory approval for and successfully commercializing our most advanced candidate, envu, either alone or with third parties. However, our operations may not be profitable even if envu is successfully developed, approved and thereafter commercialized.

We have and will continue to incur significant development and other expenses related to our research and clinical development programs and ongoing operations. For the years ended December 31, 2025 and 2024, our net losses were $243.3 million and $294.2 million, respectively. As of December 31, 2025, we had an accumulated deficit of $901.9 million. Substantially all of our losses have resulted from expenses incurred in connection with the acquisition and development of our pipeline and from general and administrative costs associated with our operations. We expect to incur significant losses for the foreseeable future, and we expect these losses to increase as we continue our development of our product candidates.

We anticipate that our expenses will increase substantially if, and as, we:

- conduct preclinical studies and clinical trials for envu, A-005, and potential future programs;
- identify additional product candidates and acquire rights from third parties to those product candidates through licenses or other acquisitions, and conduct development activities, including preclinical studies and clinical trials;
- procure the manufacturing of preclinical, clinical and commercial supply of our current and future product candidates;
- seek regulatory approvals for our product candidates or any future product candidates;
- commercialize our current product candidates or any future product candidates, if approved;
- take steps toward our goal of being an integrated biopharma company capable of supporting commercial activities, including establishing sales, marketing and distribution infrastructure;
- attract, hire and retain qualified clinical, scientific, operations and management personnel;

- add and maintain operational, financial and information management systems;
- protect, maintain, enforce and defend our rights in our intellectual property portfolio;
- defend against third-party interference, infringement and other intellectual property claims, if any;
- address any competing therapies and market developments;
- experience any delays in our preclinical studies or clinical trials and seeking regulatory approval for our product candidates due to public health concerns, macroeconomic conditions or geopolitical conflicts; and
- incur costs associated with operating as a public company.

Even if we succeed in commercializing one or more product candidates, we expect to incur substantial development costs and other expenditures to develop and market additional product candidates. We may also encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue or raise additional capital. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and our working capital.

We could also encounter delays if a clinical trial is suspended, put on clinical hold or terminated by us, the IRBs or ethics committees of the institutions in which such trials are being conducted, the FDA, or other comparable foreign regulatory authorities, or if a clinical trial is recommended for suspension or termination by the Data Safety Monitoring Board for such trial. A suspension, clinical hold or termination may be imposed due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, failure by our contract research organizations ("CROs") or clinical trial sites to perform in accordance with GCPs, or applicable regulatory guidelines in other countries, inspection of the clinical trial operations or trial site by the FDA or other comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to establish or achieve clinically meaningful trial endpoints, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Clinical trials may also be delayed or terminated as a result of ambiguous or negative interim results. For example, we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success despite safety results consistent with envu's safety profile in psoriasis patients. 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 regulatory approval of our product candidates. Further, the FDA or other comparable foreign regulatory authorities may disagree with our clinical trial design and our interpretation of data from clinical trials, or may change the requirements for approval even after they have reviewed and commented on the design for our clinical trials.

We may also, in the future, conduct preclinical and clinical research in collaboration with other academic, pharmaceutical and biotechnology entities in which we combine our research or development efforts with those of our collaborators. Such collaborations may be subject to additional delays because of the management of the trials, contract negotiations, the need to obtain agreement from multiple parties and may increase our future costs and expenses.

Our product development costs will increase if we experience delays in clinical testing or regulatory approvals. We do not know whether any of our clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates and may allow our competitors to bring products to market before we do, potentially impairing our ability to successfully commercialize our product candidates. Any delays or increase in costs in our clinical development programs may harm our business, financial condition, results of operations and prospects.

Enrollment and retention of participants in clinical trials is an expensive and time-consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying

patients, the availability of competitive products and significant competition for recruiting participants in clinical trials.

Participant enrollment, a significant factor in the timing of clinical trials, is affected by many conditions, including the size and nature of the patient population, the number and location of clinical sites we enroll, the proximity of participants to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the inability to obtain and maintain participant consents, the risk that enrolled participants will drop out before completion, competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the product candidate being studied in relation to other available therapies, including any new drugs or biologics that may be approved for the indications being investigated by us. Risks related to patient enrollment are heightened in longer clinical trials, including the 48-week trial period contemplated by our ongoing Phase 2b clinical trial of envu in SLE. In particular, this trial has been and may continue to be challenging to enroll due to the fact that patients must be experiencing active disease at the time of screening to be eligible for enrollment. In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same areas as our product candidates, and this competition will reduce the number and types of participants available to us, because some participants who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors, or to use currently marketed therapies. Additionally, participants, including participants in any control groups, may withdraw from the clinical trial if they are not experiencing improvement in their underlying disease or condition or if they experience other difficulties or issues. Additionally, we could encounter delays if treating clinicians encounter unresolved ethical issues associated with enrolling participants in clinical trials of our product candidates in lieu of prescribing existing treatments that have established safety and efficacy profiles.

We have in the past experienced and expect to continue to experience participant withdrawals or discontinuations from our trials. For example, as long-term treatment with envu continues to be evaluated in our STRIDE OLE, ONWARD3 LTE study and LUMUS Part B OLE, we expect to see discontinuation rates rise over time. Withdrawal of participants from our clinical trials may compromise the quality of our data. Even if we are able to enroll a sufficient number of participants in our clinical trials, delays in enrollment or small population size may result in increased costs or may affect the timing or outcome of our clinical trials. Any of these conditions may negatively impact our ability to complete such trials or include results from such trials in regulatory submissions, which could adversely affect our ability to advance the development of our product candidates.

We will require substantial additional financing to achieve our goals, and failure to obtain additional capital when needed, or on acceptable terms to us, could cause us to delay, limit, reduce or terminate our product development or future commercialization efforts.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through equity offerings, debt financings, or other capital sources, including potential collaborations, licenses and other similar arrangements. For example, in March 2026, we entered into a Controlled Equity Offering^{SM} Sales Agreement (as amended from time to time, the "Sales Agreement") with Cantor Fitzgerald & Co. ("Cantor"), pursuant to which we may offer and sell, from time to time through Cantor, at our option, shares of our common stock having an aggregate offering price of up to $300.0 million. To the extent that we raise additional capital through the sale of equity or convertible debt securities, including pursuant to sales under the Sales Agreement, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of our common stock. Any future 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, selling or licensing our assets, making capital expenditures, declaring dividends or encumbering our assets to secure future indebtedness. Such restrictions could adversely impact our ability to conduct our operations and execute our business plan. We could also be required to seek collaborators for product candidates at an earlier stage than otherwise would be desirable or on terms that are less favorable than might otherwise be available or relinquish or license on unfavorable terms our rights to product candidates in markets where we otherwise would seek to pursue development or commercialization ourselves.

Based on our current operating plan, we will need to raise additional financing to continue our products' development for the foreseeable future, and until we become profitable, if ever. Any additional fundraising efforts may divert our management from our day-to-day activities, which may adversely affect our ability to develop and commercialize product candidates. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to obtain funding when and as needed on a timely basis, we may be required to significantly curtail, delay or discontinue

one or more of our research or development programs or the commercialization of any product candidate, or be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations. Any of the above events could significantly harm our business, prospects, financial condition and results of operations and cause the price of our common stock to decline.

Risks Related to Product Candidate Development and Commercialization

Preclinical and clinical development involves a lengthy and expensive process, with an uncertain outcome, and results of earlier studies and trials may not be predictive of future trial results. We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our current product candidates or any future product candidates.

Our product candidates are either in clinical or preclinical development, and their risk of failure is high. It is impossible to predict when or if our product candidates will receive regulatory approval. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and lengthy, complex and expensive clinical trials that our product candidates are safe and effective in humans for their intended uses. Before obtaining approval from regulatory authorities for the commercialization of any of our product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidate in humans. Before we can initiate clinical trials for any product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate chemistry, manufacturing and controls and our proposed clinical trial protocol, as part of an IND application or similar regulatory submission. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any product candidate before allowing us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays and increase the costs of our preclinical development programs.

Once initiated, clinical testing can take many years to complete, and its outcome is inherently uncertain. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials and results in one indication may not be predictive of results to be expected for the same product candidate in another indication. For example, while we plan to continue to evaluate the development program for lonigutamab, which was ACELYRIN's lead product candidate, and its potential differentiation in a capital efficient manner, lonigutamab's potential to improve on the safety and side-effect profile of the sole currently-approved therapy in the United States for the treatment of TED is unproven. In particular, if lonigutamab is shown to have similar adverse events or side effects as the existing therapy, or other safety or tolerability concerns, such as hearing impairment, then our opportunity to disrupt the current standard of care in TED will be limited or precluded altogether. In this regard, ACELYRIN observed certain adverse events in its Phase 2 clinical trial of lonigutamab including, without limitation, headache, tinnitus and injection site reactions. If we determine that, whether due to emerging clinical data or otherwise, any of our drug candidates will be unable to improve on the current standard of care in the indications we are pursuing, we may decide to modify, suspend or abandon such development program. Differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unfavorable safety profiles, notwithstanding promising results in earlier trials, and we have experienced and may experience setbacks in our programs in the future. For example, we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success despite safety results consistent with envu's safety profile in psoriasis patients. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain regulatory approval of such product candidates.

Commencing any future clinical trials is subject to finalizing the trial design and submitting an application to the FDA or a comparable foreign regulatory authority. Even after we make our submission, the FDA or comparable foreign regulatory authorities could disagree that we have satisfied their requirements to commence our clinical trials or disagree with our study design, which may require us to complete additional trials or amend our protocols or impose stricter conditions on the commencement of clinical trials. There is typically a high rate of failure of product candidates proceeding through clinical trials, and failure can occur at any time during the clinical trial process. Most product candidates that commence

clinical trials are never approved as products and there can be no assurance that any of our current or future clinical trials will ultimately be successful or support the approval of our current or any future product candidates.

We expect to continue to rely on our CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, including the participant enrollment process, and we have limited influence over their performance. We or any future collaborators may experience delays in initiating or completing clinical trials due to unforeseen events or otherwise, that could delay or prevent our ability to receive regulatory approval or commercialize our current and any future product candidates, including:

- we may be unable to generate sufficient preclinical, toxicology, or other *in vivo* or *in vitro* data to support the initiation or continuation of clinical trials;
- regulators, such as the FDA or comparable foreign regulatory authorities, may disagree with the design or implementation of our clinical trials;
- regulators, such as the FDA or comparable foreign regulatory authorities, IRBs, or ethics committees may impose additional requirements before permitting us to initiate a clinical trial, may not allow us or our investigators to commence or conduct a clinical trial at a prospective trial site, may not allow us to amend trial protocols, or may require that we modify or amend our clinical trial protocols;
- we may experience delays in reaching, or fail to reach, agreement on acceptable terms with trial sites and CROs, the terms of which can be subject to extensive negotiation and may vary significantly;
- we may be unable to identify, recruit, or train suitable clinical investigators;
- clinical trial sites may deviate from trial protocol or drop out of a trial;
- we may be unable to complete our clinical trials due to trial participant withdrawals and discontinuations due to AEs;
- the number of participants required for clinical trials may be larger than we anticipate, enrollment in clinical trials may be slower than we anticipate or participants may drop out or fail to return for post-treatment follow-up at a higher rate than we anticipate;
- the cost of clinical trials may be greater than we anticipate, or we may have insufficient funds to initiate or complete a clinical trial or to pay the substantial user fees required by the FDA upon the submission of an NDA or comparable marketing authorization application in another jurisdiction;
- the quality or quantity of data relating to our product candidates or other materials necessary to conduct our clinical trials may be inadequate to initiate or complete a given clinical trial;
- reports from clinical testing of other therapies may raise safety, tolerability or efficacy concerns about our product candidates;
- clinical trials of our product candidates may fail to show appropriate safety, tolerability or efficacy, may produce negative or inconclusive results, or may otherwise fail to improve on the existing standard of care, and we may decide, or regulators may require us, to conduct additional clinical trials or we may decide to abandon product development programs;
- our CROs or clinical trial sites may fail to perform in accordance with GCP requirements or other applicable regulations, rules or guidelines;
- we may be unable to manufacture our product candidates from our contract manufacturing organizations

("CMOs") in accordance with cGMP regulations or other applicable requirements in sufficient quantities for use in our clinical trials;

- SAEs may occur in trials of the same class of agents conducted by other companies that could be considered similar to our product candidates;

- we may select clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data;

- we may be required to transfer our manufacturing processes to larger-scale facilities operated by a different CMO, or may experience delays or failure by our CMOs or us to make any necessary changes to such manufacturing process; and

- third parties may be unwilling or unable to satisfy their contractual obligations to us in a timely manner.

In addition, we have historically leveraged our extensive analyses of immune-relevant GWAS results from both the public domain and the UK Biobank biomedical resource to identify the right therapeutic target on which to focus our preclinical and clinical development efforts. If our access to GWAS results from the public domain or the UK Biobank biomedical resource were to be restricted, including as a result of any potential future legislative policies or regulations that may seek to restrict the sharing of genetic data, our ability to efficiently identify additional therapeutic targets may be limited.

In addition, the FDA's and other regulatory authorities' policies with respect to clinical trials may change and additional government regulations may be enacted. In the EU, the EU Clinical Trials Regulation ("CTR") became applicable on January 31, 2022, repealing and replacing the Clinical Trials Directive ("CTD"). The CTR permits trial sponsors to make a single submission to both the competent authority and an ethics committee in each EU member state, leading to a single decision for each EU member state. The assessment procedure for the authorization of clinical trials has been harmonized as well, including a joint assessment of some elements of the application by all EU member states in which the trial is to be conducted, and a separate assessment by each EU member state with respect to specific requirements related to its own territory, including ethics rules. Each EU member state's decision is communicated to the sponsor through a centralized EU portal, the Clinical Trial Information System. The CTR foresaw a three-year transition period that ended on January 31, 2025. Since this date, all new or ongoing trials are subject to the provisions of the CTR.

Moreover, following a public consultation that began in 2022, the United Kingdom government has enacted new legislation to overhaul the clinical trials regulatory framework. In April 2025, the UK adopted an amendment to the Medicines for Human Use (Clinical Trials) Regulations 2004 intended to support a more streamlined and flexible regulation of clinical trials, remove unnecessary administrative burdens on trial sponsors, and protect the interests of trial participants. It also intends to bring the UK regulatory framework for clinical trials into closer alignment with the CTR. The amendment will become applicable on April 28, 2026 following a one-year transition period. While these changes introduce efficiencies and align with some principles of the EU's CTR, divergence between the United Kingdom and EU regulatory systems remains. Any significant divergence could affect the cost and complexity of conducting clinical trials in the United Kingdom and may impact the acceptability of United Kingdom-based trial data for seeking marketing authorizations in the EU, and vice versa.

Our clinical trials may reveal SAEs and AEs and may result in a safety or tolerability profile that could delay or prevent regulatory approval or market acceptance of envu, A-005 or any future product candidates.

Undesirable or clinically unmanageable side effects observed in our clinical trials for our product candidates could occur and cause us or regulatory authorities to interrupt, delay or halt our clinical trials and could result in a more restrictive labeling or the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

We have observed SAEs and AEs in our trials of envu, and as more patients become exposed to envu over longer periods of time, we expect to see additional SAEs and AEs emerge. Further, long term treatment with envu continues to be evaluated in an OLE trial, and additional AEs and SAEs will continue to accumulate. Certain conditions occur more

frequently in patients with psoriasis compared to the general population. Examples include obesity, cardiovascular disease, psoriatic arthritis and depression. Immune modulating treatments including envu may result in increasing susceptibility to various infections, including serious or life-threatening infections, and there is a theoretical risk with immune-modulating agents that dampening immune responses could increase the risk of malignancies.

Other TYK2 inhibitors, such as deucravacitinib (marketed as Sotyktu), which is approved for the treatment of adults with PsO, have shown AEs such as hypersensitivity reactions, infections, tuberculosis, malignancy and rhabdomyolysis. The label for deucravacitinib includes a warning concerning the potential for JAK-related AEs, such as cardiovascular and thrombotic events. We have observed, and expect that additional AEs and SAEs consistent with known side effects of TYK2 inhibition may emerge, in our ongoing and future clinical trials of envu.

The most common AEs observed in our Phase 2 STRIDE and OLE PsO trials that were considered related to envu treatment by the principal investigator include headaches, upper respiratory tract infections, nasopharyngitis, rash and nausea. We continue to evaluate the safety profile of envu in our ongoing Phase 2 OLE and Phase 3 trials.

If AEs, SAEs or other side effects are observed in any of our ongoing or future clinical trials that are atypical of, or more severe than, the known side effects of the respective class of agents that each of our product candidates are a part of, we may have difficulty recruiting participants to our clinical trials, participants may drop out of our trials, or we may be required to abandon those trials or our development efforts of one or more product candidates altogether. If such effects are more severe or less reversible than we expect, or not reversible at all, we may decide or be required to perform additional studies or to halt or delay further clinical development of envu, A-005 or any future product candidates, which could result in the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities.

If envu fails to demonstrate an acceptable benefit/risk profile, versus current approved therapies or others in clinical development, then our opportunity to disrupt the current standard of care may be limited. AEs and SAEs that emerge during clinical investigation of or treatment with envu, A-005, or any future product candidates have in the past been and may in the future be deemed to be related to our product candidates. This may require longer and more extensive clinical development, or regulatory authorities may increase the amount of data and information required to approve, market, or maintain envu, A-005 or any future product candidates and could result in warnings and precautions in our product labeling or a restrictive REMS or comparable foreign strategies. This may also result in an inability to obtain approval of envu, A-005 or any future product candidates. We, the FDA or other comparable foreign regulatory authorities, or an IRB or ethics committee, may suspend clinical trials of a product candidate at any time for various reasons, including a belief that participants in such trials are being exposed to unacceptable health risks or adverse side effects. Some potential product candidates developed in the biotechnology industry that initially showed promise in early-stage trials have later been found to cause side effects that prevented their further development. Even if the side effects do not preclude the product candidate from obtaining or maintaining regulatory approval, undesirable side effects, like those mentioned above, may limit market acceptance of the approved product due to its tolerability versus other therapies. Any of these developments could materially harm our business, financial condition, results of operations and prospects.

Additionally, if any of our product candidates receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result. For example, the FDA could require us to adopt a REMS, to ensure that the benefits of treatment with such product candidate outweigh the risks for each potential patient, which may include, among other things, a communication plan to health care practitioners, patient education, extensive patient monitoring or distribution systems and processes that are highly controlled, restrictive and more costly than what is typical for the industry. We or our collaborators may also be required to adopt a REMS or comparable foreign strategies or engage in similar actions, such as patient education, certification of health care professionals or specific monitoring, if we or others later identify undesirable side effects caused by any product that we develop alone or with collaborators. Other potentially significant negative consequences associated with AEs include:

- we may be required to suspend marketing of a product, or we may decide to remove such product from the marketplace;

- regulatory authorities may withdraw, suspend or change their approvals of a product;

- regulatory authorities may require additional warnings on the label or limit access of a product to selective specialized centers with additional safety reporting and with requirements that patients be geographically close to these centers for all or part of their treatment; and

- we may be required to create a medication guide outlining the risks of a product for patients, or to conduct post-marketing studies.

Any of these events could diminish the usage or otherwise limit the commercial success of our product candidates and prevent us from achieving or maintaining market acceptance of our product candidates, if approved by the FDA or comparable foreign regulatory authorities.

Preliminary, "top-line" and interim data from our clinical trials that we announce or publish from time to time may change as more patient data become available or 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 preliminary or top-line data from our preclinical studies and clinical trials, which are based on preliminary analyses of then-available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular preclinical study or clinical trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, and we may not have received or had the opportunity to fully and carefully evaluate all data. As a result, the top-line or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Top-line and preliminary 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, top-line and preliminary data should be viewed with caution until the final data are available.

From time to time, we may also disclose data from interim analyses from our clinical trials. Interim analyses from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as participants enrollment continues and more participant data become available or as participants from our clinical trials continue other treatments for their disease. Adverse differences between interim data, topline data, or preliminary data and final data could significantly harm our business prospects.

Further, others, including regulatory authorities, 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 value of the particular program, the approvability or commercialization of the particular product candidate and could adversely affect the success of our business. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure.

If the interim, top-line or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Further, disclosure of interim, top-line or preliminary data by us or by our competitors could result in volatility in the price of our common stock.

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

We have conducted, are currently conducting, and may in the future conduct, clinical trials outside the United States, including (without limitation) in the EU, the UK, Japan, Latin America and APAC countries. We expect to continue to conduct trials internationally in the future. The acceptance of data from clinical trials conducted outside the United States

or another jurisdiction by the FDA or comparable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the U.S. population and U.S. medical practice and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations and (iii) the data may be considered valid without the need for an on-site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on-site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, the FDA will not accept the data as support for an application for regulatory approval unless the study is well-designed and well-conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. In addition, such foreign trials are subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which could be costly and time-consuming, and which may result in current or future product candidates that we may develop being delayed or not receiving approval for commercialization in the applicable jurisdiction.

Even if we receive regulatory approval for our current or future product candidates in the United States, we may never receive regulatory approval to market outside of the United States.

We plan to seek regulatory approval for our current and future product candidates outside of the United States and are currently conducting certain clinical trials internationally, including in the EU and Japan. In order to market any product outside of the United States, however, we must establish and comply with the numerous and varying safety, efficacy and other regulatory requirements of other applicable countries. Approval procedures vary among countries and can involve additional product candidate testing and additional administrative review periods. The time required to obtain approvals in other countries might differ substantially from that required to obtain FDA approval. The regulatory approval processes in other countries generally implicate all of the risks detailed above regarding FDA approval in the United States as well as other risks. In particular, in many countries outside of the United States, products must receive pricing and reimbursement approval before the product can be commercialized. Obtaining this approval can result in substantial delays in bringing products to market in such countries. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others and would impair our ability to market our current or future product candidates in such foreign markets. Any such impairment would reduce the size of our potential market, which could adversely affect our business, financial condition, results of operations and prospects.

The successful commercialization of our product candidates, if approved, will depend in part on the extent to which governmental authorities and health payors and insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our product candidates could limit our ability to market those products and decrease our ability to generate revenue.

The availability of coverage and the adequacy of reimbursement by governmental healthcare programs, such as Medicare and Medicaid, private health insurers and other third-party payors are essential for most patients to be able to afford prescription medications such as our product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third-party payors will have an effect on our ability to successfully commercialize those products. Even if we obtain coverage for a given product by a third-party payor, the resulting reimbursement payment rates may not be adequate or may require co-payments that patients find unacceptably high. We cannot be sure that coverage and reimbursement in the United States, the EU, Japan or elsewhere will be available for any product that we may develop, and any reimbursement that may become available may be decreased or eliminated in the future.

Third-party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third-party payors may refuse to provide coverage and reimbursement for particular drugs when equivalent generic drugs, biosimilars or less expensive therapies are available. It is possible that a third-party payor may consider our product candidates, if approved, as substitutable and only be willing to cover the cost of the alternative product. Even if we show

improved efficacy, safety or improved convenience of administration with envu, A-005 or any of our future product candidates, if approved, pricing of competitive products may limit the amount we will be able to charge for our product candidates, if approved. Third-party payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in our product candidates. In some cases, when new competitor generic and biosimilar products enter the market, there are mandatory price reductions for the innovator compound. In other cases, payors employ "therapeutic category" price referencing and seek to lower the reimbursement levels for all treatments in the respective therapeutic category. Additionally, new competitor brand drugs can trigger therapeutic category reviews in the interest of modifying coverage and/or reimbursement levels. The potential of third-party payors to introduce more challenging price negotiation methodologies could have a negative impact on our ability to successfully commercialize our product candidates, if approved.

There is significant uncertainty related to third-party payor coverage and reimbursement of newly approved products. In the United States, third-party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third-party payors may require pre-approval of coverage for new or innovative devices or therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third-party payors will decide with respect to the coverage and reimbursement for our products, if approved.

Obtaining and maintaining reimbursement status is time consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third-party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, in some cases on short notice, and we believe that changes in these rules and regulations are likely.

Outside the United States, biopharmaceutical products and services are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe and other countries will continue to put pressure on the pricing and usage of our product candidates. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Some countries provide that products may be marketed only after an agreement on reimbursement price has been reached. Such pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Other countries allow companies to establish their own prices for medical products but monitor and control company profits or control prescription volumes and issue guidance to physicians to limit prescriptions. In addition, some EU member states may require the completion of additional studies that compare the cost-effectiveness of a particular medicinal product candidate to currently available therapies. This HTA process is the procedure according to which the assessment of the public health impact, therapeutic impact and the economic and societal impact of use of a given medicinal product in the national healthcare systems of the individual country is conducted. The outcome of HTA regarding specific medicinal products will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states.

Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our product candidates, if approved. In December 2021, the HTA Regulation was adopted. The HTA Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products, and provide the basis for cooperation at EU level for joint clinical assessments in these areas. The HTA Regulation entered into application on January 12, 2025 and has a phased implementation. Individual EU member states continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies, and making decisions on pricing and reimbursement.

Further, the containment of health care costs also has become a priority of federal, state and foreign governments and the

prices of products have been a focus in this effort. For example, the 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 years and biologics that have been on the market for at least 11 years covered under Medicare as part of the Medicare Drug Price Negotiation Program. Each year up to 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. Such increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of our product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, particularly prescription drugs and surgical procedures and other treatments, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. There can be no assurance that any country that has reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our products, if approved in those countries. In the event Most-Favored-Nation pricing for pharmaceutical products is implemented and applicable to any of product candidates that may receive regulatory approval, our revenue opportunities may be adversely affected, as our U.S. pricing would have to be reduced to the lowest price paid for the applicable product outside of the United States. In such event, we may choose to forgo the ex-U.S. market to preserve more favorable U.S. pricing.

We face competition from entities that have made substantial investments into the rapid development of competitor treatments for immunological indications, including large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in our current indications.

The development and commercialization of therapies is highly competitive. Our product candidates, if approved, will face significant competition, including from well-established, currently marketed therapies, and our failure to demonstrate a meaningful improvement to the existing standard of care may prevent us from achieving significant market penetration. Many of our competitors have significantly greater resources and experience than we do, and we may not be able to successfully compete. We face substantial competition from multiple sources, including large and specialty pharmaceutical and biotechnology companies, academic research institutions and governmental agencies and public and private research institutions. Our competitors compete with us on the level of the technologies employed, or on the level of development of their products as compared to our product candidates. In addition, many small biotechnology companies have formed collaborations with large, established companies to (i) obtain support for their research, development and commercialization of products or (ii) combine several treatment approaches to develop longer lasting or more efficacious treatments that may potentially directly compete with our current or any future product candidates. We anticipate that we will continue to face increasing competition as new therapies and combinations thereof, and related data, emerge.

Our current product candidates initially under development for treatment of patients with immune-mediated diseases, if approved, would face competition from existing approved immunological treatments, many of which have achieved commercial success. For example, we are currently developing envu for the treatment of PsO and SLE. Other emerging and established life sciences companies have been focused on similar therapeutics and indications. If approved, envu would compete with several currently approved or late-stage oral clinical therapeutics in each such indication as well as other drugs used to treat such patients.

We are also developing A-005, which has potential applications in MS and other neuroinflammatory and neurodegenerative diseases. There are several therapies available for the treatment of relapsing forms of MS, including interferon beta regulators, monoclonal antibodies, synthetic immunomodulatory drugs and S1P receptor modulators.

To compete successfully, we need to disrupt these currently marketed drugs, meaning that we will have to demonstrate that the relative cost, method of administration, safety, tolerability and efficacy of our product candidates provide a better alternative to existing and new therapies. Our commercial opportunity and likelihood of success will be reduced or eliminated if our product candidates are not ultimately demonstrated to be safer, more effective, more conveniently administered, or less expensive than the current standard of care. Furthermore, even if our product candidates are able to achieve these attributes, acceptance of our products may be inhibited by the reluctance of physicians to switch from

existing therapies to our products, or if physicians choose to reserve our products for use in limited circumstances.

Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we have. If we obtain regulatory approval for any product candidate, we will face competition based on many different factors, including the safety and effectiveness of our current or any future product candidates, the ease with which our current or any future product candidates can be administered and the extent to which participants accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, less expensive or marketed and sold more effectively than any products we may develop. Competitive products may make any products we develop obsolete or noncompetitive before we recover the expense of developing and commercializing our current or any future product candidates. Such competitors could also recruit our employees, which could negatively impact our level of expertise and our ability to execute our business plan.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified management and other personnel in establishing clinical trial sites and enrolling patients in clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

Risks Related to Our Business and Operations

We are subject to various risks related to the acquisition of ACELYRIN.

We completed the acquisition of ACELYRIN on May 21, 2025. Risks, contingencies and other uncertainties that could adversely affect our business, financial condition and results of operations following the acquisition, and any anticipated benefits of the acquisition, include:

- the effect of the ACELYRIN Merger on our ability to attract, motivate, retain and hire key personnel and maintain our relationships with suppliers, collaboration partners and others with whom we do business, or on our respective operating results and business generally;
- the diversion of our management's attention from our ongoing business operations;
- the risk that the anticipated benefits of the ACELYRIN Merger may otherwise not be fully realized; and
- risks that costs and charges and other liabilities may be greater than anticipated or incurred in different periods than anticipated.

Our business is highly dependent on the success of our most advanced product candidate, envu, and we cannot guarantee that envu will successfully complete development, receive regulatory approval or be successfully commercialized. If we are unable to develop, receive regulatory approval for, and ultimately successfully commercialize our product candidates, or if we experience significant delays in doing so, our business will be materially harmed.

We currently have no products approved for commercial sale or for which regulatory approval to market has been sought. We have invested a significant portion of our efforts and financial resources in the development of our most advanced product candidate, envu, which is still in clinical development, and expect that we will continue to invest heavily in envu, as well as our second product candidate, A-005, and any future product candidates we may develop. Additionally, we are evaluating the development program for lonigutamab, ACELYRIN's lead product candidate, and its potential differentiation in a capital efficient manner. Our business and our ability to generate revenue, which we do not expect will occur for many years, if ever, are substantially dependent on our ability to develop, obtain regulatory approval for, and then successfully commercialize our product candidates, which may never occur.

Our product candidates will require substantial additional preclinical and clinical development time, regulatory approval, commercial manufacturing arrangements, establishment of a commercial organization, significant marketing efforts, and further investment before we can generate any revenue from product sales. We currently generate no revenue, and we may never be able to develop or commercialize any products. We cannot assure you that we will meet our timelines for our current or future clinical trials, which may be delayed or not completed for a number of reasons, including the negative impacts of geopolitical instability, public health crises, labor shortages, inflation or other macroeconomic factors impacting our third-party CROs, CMOs, clinical trial sites, investigators or us. Our product candidates are susceptible to the risks of failure inherent at any stage of product development, including the appearance of unexpected AEs or failure to achieve primary endpoints in clinical trials. For example, we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success despite safety results consistent with envu's safety profile in psoriasis patients. Additionally, we may in the future advance envu, A-005 or future product candidates into clinical trials and terminate such trials prior to their completion.

Even if our product candidates are successful in clinical trials, we are not permitted to market or promote our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive sufficient regulatory approval that will allow us to successfully commercialize any product candidates. If we do not receive FDA or comparable foreign regulatory approval with the necessary conditions to allow commercialization, we will not be able to generate revenue from those product candidates in the United States or elsewhere in the foreseeable future, or at all. Any significant delays in obtaining approval for and commercializing our product candidates could adversely affect our business, financial condition, results of operations and prospects.

We have not previously submitted an NDA or similar marketing application to the FDA or comparable foreign regulatory authorities for any product candidate, and we cannot be certain that our current or any future product candidates will be successful in clinical trials or receive regulatory approval. Although we plan to submit an NDA for envu for PsO in the second half of 2026, we will need to meet with the FDA and they may raise concerns or requirements that delay submission beyond our anticipated timeline. The FDA may also consider its approvals of competing products, which may alter the treatment landscape concurrently with their review of any NDA we may submit, and which may lead to changes in the FDA's review requirements that have been previously communicated to us and our interpretation thereof, including changes to requirements for clinical data or clinical study design. Such changes could delay approval or necessitate withdrawal of any such NDA submission. Similar risks may exist in foreign jurisdictions.

If approved for marketing by applicable regulatory authorities, our ability to generate revenue from our product candidates will depend on our ability to:

- price our products competitively such that third-party and government reimbursement permits broad product adoption;
- demonstrate the superiority of our products compared to the standard of care, as well as to other therapies in development;
- create market demand for our product candidates through our own marketing and sales activities, and any other arrangements to promote these product candidates that we may otherwise establish;
- receive regulatory approval for the targeted patient populations and claims that are necessary or desirable for successful marketing;
- effectively commercialize any of our products that receive regulatory approval;
- manufacture product candidates through CMOs in sufficient quantities and at acceptable quality and manufacturing cost to meet commercial demand at launch and thereafter;
- establish and maintain agreements with wholesalers, distributors, pharmacies, and group purchasing

organizations on commercially reasonable terms;

- obtain, maintain, protect and enforce patent and other intellectual property protection and regulatory exclusivity for our products;

- achieve market acceptance of our products by patients, the medical community, and third-party payors;

- maintain a distribution and logistics network capable of product storage within our specifications and regulatory guidelines, and further capable of timely product delivery to commercial clinical sites; and

- assure that our product will be used as directed and that additional unexpected safety risks will not arise.

The regulatory approval processes of the FDA and comparable foreign authorities are lengthy, time consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for our product candidates, our business will be substantially harmed.

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates are subject to extensive regulation by the FDA in the United States and by comparable foreign regulatory authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive regulatory approval of an NDA or BLA from the FDA. Similar approvals are required in order to market product candidates in foreign countries. The process of obtaining such regulatory approval is expensive, often takes many years following the commencement of clinical trials and can vary substantially based upon the type, complexity and novelty of the product candidates involved, as well as the target indications and patient population. Approval policies or regulations may change, and the FDA and comparable foreign regulatory authorities have substantial discretion in the approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons.

Prior to obtaining approval to commercialize a product candidate in the United States or abroad, we must demonstrate based on adequate and well-controlled clinical trials, and to the satisfaction of the FDA or comparable foreign regulatory authorities, that such product candidates are safe and effective for their intended uses. Clinical testing is expensive, time consuming and subject to uncertainty. We cannot guarantee that any current or future clinical trials will be conducted as planned or completed on schedule, if at all, or that our product candidates will receive regulatory approval. Even though our topline data readout of our Phase 3 pivotal trials of envu in PsO were positive, they may not be sufficient for approval of envu in that disease, and our Phase 3 LTE trial in PsO remains ongoing. Although we have discussed and intend to further discuss our Phase 3 clinical trial design and overall development plan with the FDA to align on its sufficiency to support an NDA submission, the feedback is typically non-binding and dependent on the strength of the ultimate clinical data and the FDA's perspective on the benefit-risk profile of the treatment in the intended population. For example, the Committee for Medicinal Products for Human Use in the EU provided comments on the length of our two pivotal 24-week Phase 3 trials, and we plan to address their feedback with our comparator trials. These modifications could delay our development timelines for EU regulatory approval and require substantially more resources. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. In addition, we have initiated a Phase 2b trial of envu in SLE. Even as these trials progress, issues may arise that could require us to suspend or terminate such clinical trials or could cause the results of one cohort to differ from a prior cohort. For example, we may experience slower than anticipated enrollment in our clinical trials, which may consequently delay our development timelines or permit competitors to obtain approvals that may alter our strategy. A failure of one or more clinical trials can occur at any stage of testing, and our future clinical trials may not be successful.

In addition, even if such clinical trials are successfully completed, we cannot guarantee that the FDA or comparable foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit our product candidates for approval. To the extent that the results of the clinical trials are not satisfactory to the FDA or comparable foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional clinical trials in support of potential approval of our product candidates.

In addition, if the FDA or comparable foreign regulatory authorities grant approval for our product candidates, then, as a condition for approval, the FDA or comparable foreign regulatory authorities may require us to perform costly post-marketing testing, including Phase 4 clinical trials or surveillance to monitor the effects of the marketed product.

Our clinical trial results may also not support approval. In addition, our product candidates could fail to receive regulatory approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that our product candidates are safe and effective for any of their proposed indications;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval, including due to the heterogeneity of patient populations, or apparent improvement in trial participants receiving placebo;
- we may be unable to demonstrate that our product candidates' clinical and other benefits outweigh their safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- The data collected from clinical trials of our product candidates may not be sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of an NDA or other comparable submission in foreign jurisdictions or to obtain regulatory approval in the United States or elsewhere;
- such authorities may disagree with us regarding the formulation, labeling and/or the product specifications of our product candidates;
- approval may be granted only for indications that are significantly more limited than those sought by us, and/or may include significant restrictions on distribution and use;
- the FDA or comparable foreign regulatory authorities will review CMOs' manufacturing process and inspect our CMOs' commercial manufacturing facilities and may not approve our CMOs' manufacturing process or facilities with respect to our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval.

Even if we eventually complete clinical trials and receive approval of an NDA or comparable foreign marketing application for our product candidates, the FDA or comparable foreign regulatory authority may grant approval contingent on the performance of costly additional clinical trials and/or the implementation of a REMS or comparable foreign strategies, which may be required because the FDA or comparable foreign regulatory authority believes it is necessary to ensure safe use of the product after approval. Any delay in obtaining, or inability to obtain, applicable regulatory approval would delay or prevent commercialization of that product candidate and would materially adversely impact our business and prospects.

In addition, FDA and foreign regulatory authorities may change their policies and new regulations may be enacted. For instance, on December 11, 2025, the European Commission, the Parliament and the European Council reached a political agreement on a comprehensive overhaul of EU pharmaceutical legislation (the "Pharma Package"). The reform has been under negotiation since the European Commission submitted its proposal in April 2023. This package—comprised of a new directive and regulation to replace existing legislation—aims to modernize the EU framework. The political agreement is still subject to formal approval by the European Parliament and Council. If approved in the form proposed,

the Pharma Package will, among other changes, reduce the baseline market protection period by one year, with limited opportunities for extensions; reshape the incentives regime for orphan medicinal products; and expand the Bolar exemption. A decrease in market exclusivity opportunities for our product candidates in the EU, combined with the expanded Bolar exemption, could open them to generic or biosimilar competition earlier than under the current regime, potentially impacting reimbursement status and the commercial prospects of our product candidates.

Disruptions at the FDA and other government agencies or comparable foreign regulatory authorities caused by funding shortages, government shutdowns or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, prevent new or modified products from being developed, reviewed, approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA and comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, government shutdowns, statutory, regulatory, and policy changes, the FDA's or comparable foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or comparable foreign regulatory authorities' ability to perform routine functions. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies or comparable foreign authorities may also slow the time necessary for new drugs or modifications to approved drugs to be reviewed and/or approved by necessary government agencies or regulatory authorities, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory authorities, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the global COVID-19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations, any resurgence of the virus or emergence of new variants may lead to inspectional or administrative delays. If a prolonged government shutdown occurs, such as the U.S. government shutdown in the fourth quarter of 2025, or if global health concerns prevent the FDA or other comparable foreign regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other comparable foreign regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If our product candidates, if approved, do not achieve broad market acceptance, the revenue that we generate from their sales will be limited.

We have never commercialized a product candidate for any indication. Even if our product candidates are approved by the appropriate regulatory authorities for marketing and sale, they may not gain acceptance among physicians, patients, third-party payors and others in the medical community. If any product candidate for which we obtain regulatory approval does not gain an adequate level of market acceptance, we may not generate sufficient product revenue or become profitable.

The degree of market acceptance of our product candidates, if approved, will depend on a number of factors, some of which are beyond our control, including:

- the safety, efficacy, tolerability and ease of administration of our product candidates;
- the clinical indications for which the products are approved and the approved claims that we may make for the products;
- limitations or warnings contained in the product's approved labeling, including potential limitations on the use of the product or warnings for such products that may be more restrictive than other competitive products;
- distribution and use restrictions imposed by the FDA or comparable foreign regulatory authorities with respect to such product candidates or to which we agree as part of a mandatory REMS or risk management plan;

- changes in the standard of care for the targeted indications for such product candidates;
- the relative difficulty of administration or compliance with administration instructions of such product candidates;
- cost of treatment as compared to the clinical benefit in relation to alternative treatments or therapies;
- the availability of adequate coverage and reimbursement by third parties, such as insurance companies and other healthcare payors, and by government healthcare programs, including Medicare and Medicaid or comparable foreign programs;
- the extent and strength of our marketing and distribution of such product candidates;
- the safety, efficacy and other potential advantages of, and availability of, alternative treatments already used or that may later be approved for any of our intended indications;
- the timing of market introduction of such product candidates, as well as competitive products;
- the reluctance of physicians to switch their patients' current standard of care;
- the reluctance of patients to switch from their existing therapy regardless of the safety and efficacy of newer products;
- our ability to offer such product candidates for sale at competitive prices;
- the extent and strength of our third-party manufacturer and supplier support;
- adverse publicity about our product or favorable publicity about competitive products; and
- potential product liability claims.

Our efforts to educate the medical community and third-party payors as to the benefits of our product candidates may require significant resources and may never be successful. Even if the medical community accepts that our product candidates are safe and effective for their approved indications, physicians and patients may not immediately be receptive to such product candidates and may be slow to adopt them as an accepted treatment of the approved indications. If our current or future product candidates are approved, but do not achieve an adequate level of acceptance among physicians, patients, and third-party payors, we may not generate meaningful revenue from our product candidates and may never become profitable.

We may expend our limited resources to pursue a particular product candidate in specific indications 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 managerial resources, we focus our development efforts on certain selected product candidates in certain selected indications. For example, we are initially focused on our most advanced product candidate, envu, currently in development for the treatment of PsO and SLE, and our second product candidate, A-005, currently in development for the treatment of neuroinflammatory and neurodegenerative diseases. As a result, we may forgo or delay pursuit of opportunities with other product candidates, or other indications for our existing product candidates 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 may not yield any commercially viable product candidates. For example, we discontinued our proof-of-concept Phase 2a clinical trial of envu in patients with non-infectious uveitis in June 2024 based on the efficacy results of a data analysis prepared for a scheduled monitoring committee meeting, which efficacy results did not meet our clinical threshold for success despite safety results consistent with envu's safety profile in psoriasis

patients. 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 collaboration, licensing or other royalty arrangements in cases in which it would have been more advantageous for us to retain sole development and commercialization rights to such product candidate.

We will need to grow our organization, and we may experience difficulties in managing our growth and expanding our operations, which could adversely affect our business.

As of December 31, 2025, we employed 221 full-time and 3 part-time employees. As our development and commercialization plans and strategies develop, we expect to expand our employee base for managerial, operational, financial and other resources.

In addition, we have limited experience in manufacturing and commercialization. As our product candidates enter and advance through preclinical studies and clinical trials, we expect to continue to expand our development and regulatory capabilities and contract with other organizations to provide manufacturing and other capabilities for us. In the future, we expect to have to manage additional relationships with future collaborators or partners, suppliers and other organizations. Our ability to manage our operations and future growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. We may not be able to implement improvements to our management information and control systems in an efficient or timely manner and may discover deficiencies in existing systems and controls. Our inability to successfully manage our growth and expand our operations could adversely affect our business, financial condition, results of operations and prospects.

We are dependent on the services of our management team and other clinical and scientific personnel, and if we are not able to retain these individuals or recruit additional management or clinical and scientific personnel, our business will suffer.

Our success depends in part on our continued ability to attract, retain and motivate highly qualified management, clinical and scientific personnel. We are highly dependent upon the members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our preclinical studies and clinical trials or the commercialization of our product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain "key person" life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals.

We will need to continue to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management and scientific and clinical personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses, particularly in the greater San Francisco Bay Area. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners, CROs, CMOs and other parties. Misconduct by these parties could include intentional, reckless and/or negligent conduct that fails to comply with FDA or other regulations, provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies, respect our confidentiality and intellectual property rights, comply with manufacturing standards we may establish, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. If we obtain FDA approval for our product candidates and begin commercializing those products in the United States, our potential exposure

under these laws will increase significantly, and our costs associated with compliance with these laws are likely to increase. In particular, sales, marketing and business arrangements in the healthcare 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. Similar requirements apply in foreign countries. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. Additionally, we are subject to the risk that a person could allege such fraud or other misconduct, even if none occurred. It is not always possible to identify and deter employee 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 comply 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 material and adverse effect on our business, financial condition, results of operations and prospects, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain approvals from the FDA or comparable foreign regulatory authorities, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid or comparable foreign programs, integrity oversight and reporting obligations, or reputational harm.

International trade policies, including tariffs, sanctions and trade barriers may adversely affect our business, financial condition, results of operations and growth prospects.

We conduct business globally and our operations, including third-party suppliers, span numerous countries outside the United States. There is inherent risk, based on the complex relationships among the United States and the countries in which we conduct our business, that political, diplomatic, and national security factors can lead to global trade restrictions and changes in trade policies and export regulations that may adversely affect our business and operations. The current international trade and regulatory environment is subject to significant ongoing uncertainty. The ongoing trade tensions between the United States and other jurisdictions have resulted in multiple rounds of tariffs and potential tariffs affecting pharmaceuticals and pharmaceutical ingredients, including finished drug products, manufacturing equipment and related supplies. In April 2025, the U.S. government imposed a 10% baseline global tariff and in August 2025, the U.S. government imposed higher "reciprocal" tariffs on numerous other territories, including EU member states and South Korea. While the U.S. Supreme Court recently issued a ruling invalidating tariffs imposed by the Trump administration under the International Emergency Economic Powers Act, other tariffs imposed by the U.S. government remain in place, including the 10% global tariff imposed by the Trump administration under Section 122 of the Trade Act of 1974 following the U.S. Supreme Court decision. Moreover, the Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities. We currently rely, and expect to continue to rely, on third parties for the manufacture of our product candidates for clinical testing, as well as for manufacture of any products that we may commercialize, if approved. Currently, most of our suppliers are located outside of the United States, and our principal suppliers of critical raw materials are located in India and in Taiwan. We also rely on precursor compounds, other materials, and manufacturing services sourced from multiple countries, including the European Union and South Korea, to advance our research and development and manufacturing efforts.

Current or future tariffs will result in increased research and development expenses, including with respect to increased costs associated with APIs, raw materials, laboratory equipment and research materials and components. In addition, such tariffs will increase our supply chain complexity and could also potentially disrupt our existing supply chain. Unlike consumer goods, pharmaceuticals face unique regulatory constraints that make rapid supply chain adjustments particularly difficult and costly. Trade restrictions affecting the import of materials necessary for clinical trials could result in delays to our development timelines. Increased development costs and extended development timelines could place us at a competitive disadvantage compared to companies operating in regions with more favorable trade relationships and could reduce investor confidence, negatively impacting our ability to secure additional financing on favorable terms or at all. In addition, as we advance toward commercialization, tariffs and trade restrictions could hinder our ability to establish cost-effective production capabilities, negatively impacting our growth prospects.

The complexity of announced or future tariffs may also increase the risk that we or our customers or suppliers may be subject to civil or criminal enforcement actions in the U.S. or foreign jurisdictions related to compliance with trade regulations. Foreign governments may also adopt non-tariff measures, such as procurement preferences or informal disincentives to engage with, purchase from or invest in U.S. entities, which may limit our ability to compete internationally and attract non-U.S. investment, employees, customers and suppliers. Foreign governments may also take other retaliatory actions against U.S. entities, such as decreased intellectual property protection, increased enforcement actions, or delays in regulatory approvals, which may result in heightened international legal and operational risks. In addition, the U.S. and other governments have imposed and may continue to impose additional sanctions, such as trade restrictions or trade barriers, which could restrict us from doing business directly or indirectly in or with certain countries or parties and have imposed and may continue to impose additional costs and complexity to our business.

Trade disputes, tariffs, restrictions and other political tensions between the U.S. and other countries may also exacerbate unfavorable macroeconomic conditions including inflationary pressures, foreign exchange volatility, financial market instability, and economic recessions or downturns. The ultimate impact of current or future tariffs and trade restrictions remains uncertain and could materially and adversely affect our business, financial condition, and prospects. While we actively monitor these risks, any prolonged economic downturn, escalation in trade tensions, or deterioration in international perception of U.S.-based companies could materially and adversely affect our business, ability to access the capital markets or other financing sources, results of operations, financial condition and growth prospects. In addition, tariff and other trade developments have and may continue to heighten the risks related to the other risk factors described elsewhere in this Annual Report on Form 10-K.

Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future growth may depend, in part, on our ability to develop and commercialize our product candidates in foreign markets, including in the EU, the UK and Japan, for which we may rely on collaboration with third parties. We are not permitted to market or promote our product candidates before we receive regulatory approval from the applicable regulatory authority in that foreign market and may never receive such regulatory approval for our product candidates. To obtain separate regulatory approval in many other countries, we must comply with numerous and varying regulatory requirements of such countries regarding safety and efficacy and governing, among other things, clinical trials and commercial sales, pricing and distribution of our product candidates, and we cannot predict success in these jurisdictions. If we fail to comply with the regulatory requirements in international markets and receive applicable regulatory approvals, our target market will be reduced, our ability to realize the full market potential of our product candidates will be harmed and our business will be adversely affected. We may not obtain foreign regulatory approvals on a timely basis, if at all. Our failure to obtain approval for our product candidates by regulatory authorities in another country may significantly diminish the commercial prospects of that product candidate and our business, financial condition, results of operations and prospects could be adversely affected. Moreover, even if we obtain approval of our product candidates and ultimately commercialize our product candidates in foreign markets, we would be subject to these risks and uncertainties, including the burden of complying with complex and changing foreign regulatory, tax, accounting and legal requirements and reduced protection of intellectual property rights in some foreign countries.

Our business entails a significant risk of product liability and our ability to obtain sufficient insurance coverage could adversely affect our business, financial condition, results of operations and prospects.

As we conduct clinical trials of our current or future product candidates, we are exposed to significant product liability risks inherent in the development, testing, manufacturing and marketing of new treatments. Product liability claims could delay or prevent completion of our development programs. If we succeed in marketing products, such claims could result in FDA or other regulatory authority investigation of the safety and effectiveness of our future product candidates, our manufacturing processes and facilities or our marketing programs and potentially a recall of our products or more serious enforcement action, limitations on the approved indications for which they may be used or suspension, variation or withdrawal of approvals. Regardless of the merits or eventual outcome, liability claims may also result in decreased demand for our product candidates, termination of clinical trial sites or entire trial programs, withdrawal of clinical trial participants, injury to our reputation and significant negative media attention, significant costs to defend the related litigation, a diversion of management's time and our resources from our business operations, substantial monetary awards

to trial participants or patients, loss of revenue, the inability to commercialize and products that we may develop, and a decline in our stock price. We may need to obtain higher levels of product liability insurance for later stages of clinical development or marketing of our product candidates. Any insurance we may obtain may not provide sufficient coverage against potential liabilities. Furthermore, clinical trial and product liability insurance is becoming increasingly expensive. As a result, we may be unable to obtain sufficient insurance at a reasonable cost to protect us against losses caused by product liability claims that could adversely affect our business, financial condition, results of operations and prospects.

Our insurance policies are expensive and only protect us from some business risks, which will leave us exposed to significant uninsured liabilities.

We do not carry insurance for all categories of risk that our business may encounter. Some of the policies we currently maintain include commercial general liability, general liability, cyber liability, workers' compensation, clinical trials and directors' and officers' liability insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects.

We have engaged in, and may in the future engage in, strategic transactions, which could impact our liquidity, increase our expenses, dilute our stockholders and present significant distractions to our management.

We have in the past and may continue to enter into strategic transactions, including acquisitions of companies, asset purchases and in-licensing of intellectual property with the potential to acquire and advance new assets or product candidates where we believe we are well qualified to optimize the development of promising therapies. For example, we were founded in January 2021, and subsequently acquired envu via a stock purchase of FronThera U.S. Holdings, Inc. and its wholly owned subsidiary, FronThera U.S. Pharmaceuticals LLC. Additionally, we consummated the ACELYRIN Merger in May 2025 and acquired lonigutamab. Additional potential transactions that we may consider in the future include a variety of business arrangements, including strategic partnerships, in-licensing or out-licensing of product candidates, strategic collaborations, joint ventures, restructurings, divestitures, business combinations and investments. Any such transactions could increase our near and long-term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in-process research and development expenses, any of which could affect our financial condition, liquidity and results of operations.

Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. Even if we are able to successfully identify and acquire complementary products, technologies or businesses, we cannot assure you that we will be able to successfully manage the risks associated with integrating acquired products, technologies or businesses or the risks arising from anticipated and unanticipated problems in connection with an acquisition or in-licensing transaction. For example, as a result of the ACELYRIN Merger, we now operate our historical core business along with the acquired ACELYRIN business as one combined organization utilizing common information and communication systems, operating procedures, financial controls and human resources practices. There may be difficulties, costs and delays involved in the integration of our historical core business with the acquired ACELYRIN business, including as a result of challenges relating to the diversion of management's attention, the possibility of faulty assumptions underlying expectations regarding the integration process, retaining and attracting business and operational relationships, eliminating duplicative operations and inconsistent standards and procedures and increased or unforeseen liabilities or costs relating to the ACELYRIN Merger or the acquired ACELYRIN business. We have also incurred substantial expenses in connection with and as a result of completing the ACELYRIN Merger and may incur additional expenses as we continue to finalize integration of the businesses, operations, policies and procedures of the combined company. Further, while we seek to mitigate risks and liabilities of potential acquisitions and in-licensing transactions through, among other things, due diligence, there may be risks and liabilities that such due diligence efforts fail to discover, that are not disclosed to us, or that we inadequately assess. Any failure in identifying and managing these risks, liabilities and uncertainties effectively, including in connection with the ACELYRIN Merger, could have a material adverse effect on our business and adversely affect our results of operations and financial condition. Additionally, we may not realize the anticipated benefits of such transactions, including the possibility that expected synergies and accretion will not be realized or will not be realized within the expected time frame. Accordingly, although there can be no assurance that we

will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could adversely affect our business, financial condition, results of operations and prospects.

Our ability to use our net operating loss carryforwards and certain other tax attributes to offset taxable income or taxes may be limited.

We have incurred substantial losses during our history and do not expect to become profitable in the near future, and we may never achieve profitability. As of December 31, 2025, we had U.S. federal net operating loss carryforwards of $281.2 million and U.S. states net operating loss carryforwards of $5.9 million. Under the Internal Revenue Code of 1986, as amended (the "Internal Revenue Code"), our U.S. federal net operating losses arising in tax years beginning after December 31, 2017, will not expire and may be carried forward indefinitely, but the deductibility of such U.S. federal net operating losses in a taxable year is limited to 80% of taxable income in such year.

In addition, under Sections 382 and 383 of the Internal Revenue Code, if a corporation undergoes an "ownership change," generally defined as a greater than 50 percentage point change (by value) in its equity ownership by certain stockholders 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 or taxes may be limited. As of December 31, 2025, we completed a Section 382 analysis which indicated that we have experienced an ownership change and resulted in the expiration of U.S. federal net credits before utilization and, as such, we recognized a reduction of deferred tax assets. There may be additional ownership changes in the future, some of which may be outside of our control. If we undergo an ownership change, and our ability to use our pre-change net operating loss carryforwards and other pre-change tax attributes (such as research tax credits) to offset our post-change income or taxes (if any) is limited, such limitation could harm our future results of operations by effectively increasing our future tax obligations. Similar provisions of state tax law may also apply to limit our use of accumulated state tax attributes. In addition, at the state level, there may be periods during which the use of net operating losses is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. As a result, even if we attain profitability, we may be unable to use all or a material portion of our net operating losses and other tax attributes, which could adversely affect our future cash flows.

Recent and future changes to tax laws could materially adversely affect our company.

The tax regimes we are subject to or operate under, including with respect to income and non-income taxes, are unsettled and may be subject to significant change. Changes in tax laws, regulations or rulings, or changes in interpretations of existing laws and regulations, could materially adversely affect our company. The OBBBA enacted in July 2025, the Inflation Reduction Act ("IRA") 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 U.S. tax laws. For example, the Tax Cuts and Jobs Act required taxpayers to capitalize and amortize U.S.-based and non-U.S.-based research and experimental ("R&E") expenditures over five and fifteen years, respectively. The OBBBA restores the deductibility of domestic R&E expenditures in the year incurred for tax years beginning after December 31, 2024, but retains the capitalization and amortization requirement for foreign R&E expenditures. In addition, the IRA includes provisions that impact the U.S. federal income taxation of certain corporations, including a 15% minimum tax on the book income of certain large corporations and a 1% excise tax on certain corporate stock repurchases that is imposed on the corporation repurchasing such stock. Future guidance from the Internal Revenue Service and other tax authorities with respect to such legislation may affect us, and certain aspects thereof could be repealed or modified in future legislation, possibly with retroactive effect. Additionally, many countries in Europe, as well as a number of other countries and organizations (including the Organization for Economic Cooperation and Development and the European Commission), have proposed, recommended, or (in the case of countries) enacted changes to existing tax laws or new tax laws that could significantly increase our tax obligations in the countries where we do business or require us to change the manner in which we operate our business.

If our information technology systems, or those used by our CROs, CMOs, clinical sites or other third parties with whom we work, or our data are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, regulatory investigations or actions,

litigation, fines, penalties and liability, and other adverse consequences to our business, results of operations, and financial condition.

In the ordinary course of our business, we, and the third parties with whom we work, process personal information and other sensitive data, including intellectual property, trade secrets, proprietary or confidential business information, preclinical and clinical trial data, personal information related to relevant stakeholders, third-party data, and other sensitive data (collectively, sensitive information) and as a result, we and the third parties with whom we work face a variety of evolving threats which could cause security incidents affecting or interruptions to our information technology systems and sensitive information.

Our information technology systems and those of our CROs, CMOs, clinical sites and other third parties with whom we work are vulnerable to attack, damage and interruption from a variety of evolving threats, including but not limited to computer viruses, misconfigurations, software bugs, worms, or other vulnerabilities and malicious codes, malware (including ransomware and as a result of advanced persistent threat intrusions), application security attacks, social engineering (including through phishing attacks and deep fakes, which may be increasingly more difficult to identify as fake), supply chain attacks and vulnerabilities through our third-party service providers, denial or degradation-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, fraud, server malfunctions, software or hardware failures, loss of data or other information technology assets, attacks enhanced or facilitated by AI, adware, telecommunications and electrical failures, terrorism, war, earthquakes, fires, floods, and other similar threats. Such threats are prevalent, are occurring more often, 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. In particular, ransomware attacks, including those from organized criminal threat actors, nation-states and nation-state supported actors, are becoming increasingly prevalent and severe and can lead to significant interruptions, delays, or outages in our operations, loss of data (including sensitive information), loss of income, significant extra expenses to restore data or systems, reputational loss, the diversion of funds and other consequences. To alleviate the negative impact of a ransomware attack, it may be preferable to make extortion payments, but we may be unwilling or unable to do so (including, for example, if applicable laws or regulations prohibit such payments). 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.

Some actors also now engage and are expected to continue to engage in cyberattacks, 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 cyberattacks, that could materially disrupt our systems, operations and supply chain. 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.

Additionally, remote work has become more common and has increased risks to our information technology systems and data, as more of our personnel utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.

Furthermore, future or past business transactions (such as the ACELYRIN Merger or other 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. Additionally, 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 acquired entities into our information technology environment and security program.

We have in the past and may in the future expend significant resources and modify our business activities to try to protect against security incidents. While we take steps designed to anticipate, detect and remediate threats and vulnerabilities, because the threats and techniques used to exploit such vulnerabilities and gain unauthorized access to, to sabotage or

otherwise compromise systems change frequently, are often sophisticated in nature, and are often not recognized until launched against a target, we may be unable to anticipate these techniques or implement and maintain adequate preventative measures. Therefore, such vulnerabilities have and could be exploited but may not be detected until after a security incident has occurred. We may also experience security breaches that may remain undetected for an extended period. Even if identified, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities and we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. There can be no assurance that our information security policies, controls or procedures, will be fully implemented, complied with or effective in protecting our systems and sensitive information.

Our reliance on third-party service providers could introduce additional 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 and to process sensitive information in a variety of contexts, including, without limitation, cloud-based infrastructure, data hosting, encryption and authentication technology, personnel email, human resource management, training and other functions. We also rely on third-party service providers to assist with our clinical trials or otherwise to operate our business, including to manage and store sensitive patient data from our clinical trials. 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. Our third-party service providers have and may in the future experience a security incident or other interruption. 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 and infrastructure in our supply chain or our third-party partners' supply chains have not been compromised or that they do not contain exploitable defects or bugs that could result in a breach of or disruption to our information technology systems or the third-party information technology systems that support our operations.

We and certain of our service providers have been and are from time to time subject to cyberattacks and security incidents. Any of the previously identified or similar threats have or could cause a security incident or other interruption that resulted or results in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure, or other processing of, or access to our sensitive information or our information technology systems, or those of the third parties with whom we work. A security incident or other interruption could disrupt our ability (and that of third parties with whom we work) to conduct clinical trials. Additionally, sensitive information of the company could be leaked, disclosed, or revealed as a result of or in connection with our employees', personnel's, or vendors' use of generative AI technologies.

The costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. If the information technology systems of our CROs, CMOs, clinical sites and other third parties become subject to disruptions or security incidents, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Our contracts may not contain liability limitations and, even where they do, there can be no assurance that such limitations are sufficient to protect us from liabilities, damages or claims related to our data privacy and security obligations. Further, our cyber liability insurance coverage may not be sufficient to cover the financial, legal, business reputational or other losses that may result from an interruption or breach.

Security incidents have and could result in a disruption of our business and development programs. For example, the loss of clinical trial data from completed or ongoing clinical trials for a product candidate could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data, or may limit our ability to effectively execute a product recall, if required in the future. To the extent that any disruption or security incident were to result in the loss of or damage to our data or applications, or inappropriate disclosure of sensitive information, we could incur liability and the further development of any product candidates could be delayed.

Applicable data privacy and security obligations may require us, or we may voluntarily choose, to notify relevant stakeholders, including affected individuals, regulators, and investors, of security incidents, or take other actions, such as providing credit monitoring and identify theft protection services. Such disclosures and related actions can be costly, and the disclosure or the failure to comply with such applicable requirements could lead to adverse consequences.

Security incidents (or perceived security incidents), may result in material adverse consequences such as legal claims or proceedings, liability including litigation exposure, penalties and fines under relevant legal obligations, enforcement actions and investigations by regulatory authorities, additional reporting requirements or oversight, restrictions on processing sensitive information (including personal information), indemnification obligations, monetary fund diversions, diversion of management attention, other financial loss, and damage to our reputation and a loss of confidence in us and our ability to conduct clinical trials, which could delay the clinical development of our product candidates, and of which may adversely affect our business, results of operations or financial condition.

Our operations are predominantly concentrated in one location, and we or the third parties upon whom we depend may be adversely affected by a wildfire, earthquake or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster.

Our current operations are predominantly located in California. Any unplanned event, such as flood, wildfire, explosion, earthquake, extreme weather condition, medical epidemic, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Any similar impacts of natural or manmade disasters on our third-party service providers, such as our CMOs and CROs located globally, could cause delays in our clinical trials and may have a material and adverse effect on our ability to operate our business and have significant negative consequences on our financial and operating conditions. If a natural disaster, power outage or other event occurred that prevented us from using our clinical trial sites, impacted clinical supply or the conduct of our clinical trials, that damaged critical infrastructure, such as the manufacturing facilities of our third-party CMOs, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans that we and third parties upon whom we rely have or may have in place may prove inadequate in the event of a serious disaster or similar event. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our CMOs, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our development programs may be harmed. Any business interruption could adversely affect our business, financial condition, results of operations and prospects.

Our projections regarding the market opportunities for our product candidates may not be accurate, and the actual market for our products may be smaller than we estimate.

The precise incidence and prevalence for all the conditions we aim to address with our product candidates are unknown. Our projections of both the number of people who have these diseases, as well as the subset of people with these diseases who have the potential to benefit from treatment with our product candidates, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including sales of our competitors, scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect in general, or as to their applicability to our company. Further, new trials may change the estimated incidence or prevalence of these diseases. The total addressable market across all of our product candidates will ultimately depend upon, among other things, the diagnosis criteria included in the final labeling for each of our product candidates approved for sale for these indications, the ability of our product candidates to improve on the safety, convenience, cost and efficacy of competing therapies or therapies in development, acceptance by the medical community and patients, drug pricing and reimbursement. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our product candidates or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for our product candidates, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share.

Our cash and cash equivalents may be exposed to failure of our banking institutions.

While we seek to minimize our exposure to third-party losses of our cash and cash equivalents, we hold our balances in a number of large financial institutions. Notwithstanding, those institutions are subject to risk of failure. For example, on

March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation (the "FDIC") as receiver. Similarly, on March 12, 2023, Signature Bank was also swept into receivership. The U.S. Department of Treasury, the Federal Reserve Board (the "Federal Reserve"), and the FDIC released a statement that indicated that all depositors of SVB would have access to all of their funds, including funds held in uninsured deposit accounts, after only one business day of closure. The U.S. Department of Treasury, the FDIC and the Federal Reserve have announced a program to provide up to $25 billion of loans to financial institutions secured by certain of such government securities held by financial institutions to mitigate the risk of potential losses on the sale of such instruments, widespread demands for customer withdrawals or other liquidity needs of financial institutions for immediately liquidity may exceed the capacity of such program. There is no guarantee, however, that the U.S. Department of Treasury, the FDIC and the Federal Reserve will provide access to uninsured funds in the future in the event of the closure of other banks or financial institutions, or that they would do so in a timely fashion.

Although we expect to assess our banking relationships as we believe necessary or appropriate, our access to cash in amounts adequate to finance or capitalize our current and projected future business operations could be significantly impaired by factors that affect the financial institutions with which we have banking relationships, and in turn, us.

These factors could include, among others, events such as liquidity constraints or failures, the ability to perform obligations under various types of financial, credit or liquidity agreements or arrangements, disruptions or instability in the financial services industry or financial markets, or concerns or negative expectations about the prospects for companies in the financial services industry. These factors could also include factors involving financial markets or the financial services industry generally. The results of events or concerns that involve one or more of these factors could include a variety of material and adverse impacts on our current and projected business operations and our financial condition and results of operations. These could include, but may not be limited to, delayed access to deposits or other financial assets or the uninsured loss of deposits or other financial assets; or termination of cash management arrangements and/or delays in accessing or actual loss of funds subject to cash management arrangements.

In addition, widespread investor concerns regarding the U.S. or international financial systems could result in less favorable commercial financing terms, including higher interest rates or costs and tighter financial and operating covenants, or systemic limitations on access to credit and liquidity sources, thereby making it more difficult for us to acquire financing on acceptable terms or at all. Any decline in available funding or access to our cash and liquidity resources could, among other risks, adversely impact our ability to meet our operating expenses, financial obligations or fulfill our other obligations, result in breaches of our financial and/or contractual obligations or result in violations of federal or state wage and hour laws. Any of these impacts, or any other impacts resulting from the factors described above or other related or similar factors not described above, could have material adverse impacts on our liquidity and our current and/or projected business operations and financial condition and results of operations.

In addition, one or more of our critical vendors, third party manufacturers, or other business partners could be adversely affected by any of the liquidity or other risks that are described above, which in turn, could have a material adverse effect on our current and/or projected business operations and results of operations and financial condition. Any business partner bankruptcy or insolvency, or any breach or default by a business partner, or the loss of any significant supplier relationships, could result in material adverse impacts on our current and/or projected business operations and financial condition.

Public opinion and scrutiny of immunology treatments may impact public perception of our company and product candidates, or may adversely affect our ability to conduct our business and our business plans.

Public perception may be influenced by claims, such as claims that our product candidates are unsafe, unethical or immoral and, consequently, our approach may not gain the acceptance of the public or the medical community. Adverse public attitudes may also adversely impact our ability to enroll clinical trials. Moreover, our success will depend upon physicians specializing in the treatment of those diseases that our product candidates target prescribing, and their patients being willing to receive, treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments they are already familiar with and for which greater clinical data may be available. AEs in our clinical trials, even if not ultimately attributable to our product candidates, and the resulting publicity could result in withdrawal of clinical trial participants, increased governmental regulation, unfavorable public perception, potential regulatory delays in the testing

or approval of our product candidates, stricter labeling requirements for those product candidates that are approved and a decrease in demand for any such product candidates. In addition, side effects generally associated with TYK2 or JAK inhibitors may negatively impact public perception of us or envu and A-005. More restrictive government regulations or negative public opinion could have an adverse effect on our business, financial condition, results of operations and prospects, and may delay or impair the development and, if approved, commercialization of our product candidates or demand for any products we may develop.

The future impairment of acquired in-process research and development ("IPR&D") intangible assets related to the ACELYRIN Merger may negatively affect our results of operations and financial position.

As of December 31, 2025, we had $51.0 million of acquired IPR&D intangible assets related to the ACELYRIN Merger. In-process research and development assets are subject to an impairment analysis whenever events or changes in circumstances indicate the carrying amount of the asset may not be recoverable. Additionally, indefinite-lived assets are subject to an impairment test at least annually. Events giving rise to impairment are an inherent risk in the pharmaceutical industry and cannot be predicted. Our results of operations and financial position in future periods could be negatively impacted should future impairments of acquired IPR&D intangible assets occur.

Risks Related to Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for our product candidates and any future product candidates we may develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully develop and commercialize our product candidates may be adversely affected.

We rely upon a combination of patents, know-how and confidentiality agreements to protect the intellectual property related to our product candidates and technologies and to prevent third parties from copying and surpassing our achievements, thus eroding our competitive position in our market. Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries for our product candidates and their uses, as well as our ability to operate without infringing, misappropriating or otherwise violating the proprietary rights of others. We seek to protect our proprietary position by filing patent applications in the United States and abroad related to our product candidates and novel discoveries that are important to our business. Our pending and future patent applications may not result in patents being issued. We cannot assure you that issued patents will afford sufficient protection of our product candidates or their intended uses against competitors, nor can there be any assurance that the patents issued will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive products or product candidates.

Obtaining and enforcing patents is expensive and time-consuming, and we may not be able to file, prosecute, maintain, enforce or license all necessary or desirable patent applications or maintain and/or enforce patents that may issue based on our patent applications, at a reasonable cost or in a timely manner. We may not be able to obtain or maintain patent applications and patents due to the subject matter claimed in such patent applications and patents being in disclosures in the public domain. It is also possible that we will fail to identify patentable aspects of our research and development results before it is too late to obtain patent protection. Although we have in the past and will continue to enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, CMOs, consultants, advisors and other third parties, any of these parties may breach these agreements and disclose such results before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third parties from using any of our technology that is in the public domain to compete with our product candidates.

Composition of matter patents for pharmaceutical product candidates often provide a strong form of intellectual property protection for those types of products, as such patents provide protection without regard to any method of use. However, we cannot be certain that the claims in our pending patent applications directed to composition of matter of our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries, or that the claims in any of our issued patents will be considered valid and enforceable by courts in the United States or foreign countries. Method

of use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product candidates for an indication that is outside the scope of the patented method. Moreover, even if competitors do not actively promote their product for our targeted indications, clinicians may prescribe these products "off-label." Although off-label prescriptions may infringe or contribute to the infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions and has in recent years been the subject of much litigation, resulting in court decisions, including Supreme Court decisions, which have increased uncertainties as to the ability to enforce patent rights in the future. As a result, the issuance, scope, validity, enforceability and commercial value of any patent rights are highly uncertain. Our pending and future owned or in-licensed patent applications may not result in issued patents that protect our product candidates effectively to prevent others from commercializing our product candidates or otherwise provide any competitive advantage. In fact, patent applications may not issue as patents at all. The coverage claimed in a patent application can also be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. 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.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability and our pending patent applications may be challenged in patent offices in the United States and abroad. Even issued patents may later be found invalid or unenforceable or may be modified or revoked in proceedings instituted by third parties before various patent offices or in courts. For example, our pending patent applications may be subject to third-party pre-issuance submissions of prior art to the USPTO, or our issued patents may be subject to post-grant review ("PGR") proceedings, oppositions, derivations, reexaminations, interferences, inter partes review ("IPR") proceedings or other similar proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. Such submissions may also be made prior to a patent's issuance, precluding the granting of a patent based on one or more of our owned pending patent applications. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated, or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical product candidates, or limit the duration of the patent protection of our product candidates. Such challenges also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

A third party may also claim that our patent rights are invalid or unenforceable in a litigation. An adverse result in any legal proceeding could put one or more of our owned or patents at risk of being invalidated or interpreted narrowly and could allow third parties to commercialize our products and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize our technology, products or product candidates without infringing third-party patent rights.

In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such candidates are commercialized. The degree of future protection for our proprietary rights is uncertain. Only limited protection may be available and may not adequately protect our rights or permit us to gain or keep any competitive advantage. Any failure to obtain or maintain patent protection with respect to our product candidates or their uses could adversely affect our business, financial condition, results of operations and prospects.

We cannot ensure that patent rights relating to inventions described and claimed in our or any current or future licensors and licensees pending patent applications will issue or that patents based on our or any current or future licensors and licensees patent applications will not be challenged and rendered invalid and/or unenforceable.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our current or future licensors, licensees or collaborators will be successful in protecting our product candidates by obtaining and defending patents. We have several pending United States and foreign patent applications in our portfolio. We cannot predict:

- if and when patents may issue based on our patent applications;

- the scope of protection of any patent issuing based on our patent applications;
- whether the claims of any patent issuing based on our patent applications will provide protection against competitors;
- whether or not third parties will find ways to invalidate or circumvent our patent rights;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications;
- whether we will need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose; or
- whether the patent applications that we own will result in issued patents with claims that cover our product candidates or uses thereof in the United States or in other foreign countries.

We cannot be certain that the claims in our or any current or future licensors' pending patent applications directed to our product candidates will be considered patentable by the USPTO or by patent offices in foreign countries. There can be no assurance that any such patent applications will issue as granted patents. One aspect of the determination of patentability of our or any current or future licensors' inventions depends on the scope and content of the "prior art," information that was or is deemed available to a person of skill in the relevant art prior to the priority date of the claimed invention. There may be prior art of which we are not aware that may affect the patentability of our or any current or future licensors' patent claims or, if issued, affect the validity or enforceability of a patent claim. Even if the patents do issue based on our or any current or future licensors' patent applications, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents in our or any current or future licensors' portfolio may not adequately exclude third parties from practicing relevant technology or prevent others from designing around our claims. If the breadth or strength of our intellectual property position with respect to our product candidates is threatened, it could dissuade companies from collaborating with us to develop and threaten our ability to commercialize our product candidates. In the event of litigation or administrative proceedings, we cannot be certain that the claims in any of our issued patents will be considered valid by courts in the United States or foreign countries.

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

Patents are of national or regional effect, and filing, prosecuting and defending patents on all of our research programs and product candidates in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States, even in jurisdictions where we do pursue patent protection. Consequently, we may not be able to prevent third parties from practicing our or any current or future licensors' inventions in all countries outside the United States, even in jurisdictions where we or any current or future licensors do pursue patent protection, or from selling or importing products made using our or any current or future licensors' inventions in and into the United States or other jurisdictions. Competitors may use our or any current or future licensors' technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we or any current or future licensors have patent protection, but enforcement is not as strong as that in the United States. These competitor products may compete with our product candidates, and our or any current or future licensors' patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Various companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of many countries do not favor the enforcement of patents and other intellectual property protection, particularly those relating to pharmaceuticals, which could make it difficult for us to stop the infringement of our or any current or future licensors' patents or marketing of competing products in violation of our proprietary rights.

Certain countries outside the United States have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. As a result, a patent owner may have limited remedies in certain circumstances, which could materially diminish the value of such patent. If we or any current or future licensors are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. 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 in the future.

Further, the standards applied by the USPTO and foreign patent offices in granting patents are not always applied uniformly or predictably. As such, we do not know the degree of future protection that we will have on our product candidates. While we will endeavor to try to protect our product candidates with intellectual property rights, such as patents, as appropriate, the process of obtaining patents is time consuming, expensive and unpredictable.

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. For example:

- others may be able to make product candidates that are similar to ours but that are not covered by the pending patent applications that we own or any patents or patent applications that we currently in-license or may in-license in the future;

- we or any current or future licensors or collaborators might not have been the first to make the inventions covered by the pending patent application that we own or may in-license in the future;

- we or any current or future licensors or collaborators might not have been the first to file patent applications covering certain of our or their inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing or otherwise violating our owned intellectual property rights or any patent applications that we may license in the future;

- it is possible that noncompliance with the USPTO and foreign governmental patent agencies requirement for a number of procedural, documentary, fee payment and other provisions during the patent process can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;

- it is possible that our pending owned patent applications or those that we may own or license in the future will not lead to issued patents;

- issued patents, if any arise in the future, that we either own or that we may license in the future may be revoked, modified, or held invalid or unenforceable, as a result of legal challenges by our competitors;

- others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis;

- our competitors might conduct research and development activities 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 our major commercial markets;

- we may not develop additional proprietary technologies that are patentable;

- we cannot predict the scope of protection of any patent issuing based on our or any current or future licensors' patent applications, including whether the patent applications that we own, or, in the future, in-license will result in issued patents with claims directed to our product candidates or uses thereof in the United States or in other foreign countries;

- there may be significant pressure on the United States government and international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful, as a matter of public policy regarding worldwide health concerns;

- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidates; the claims of any patent issuing based on our patent applications may not provide protection against competitors or any competitive advantages, or may be challenged by third parties;

- if enforced, a court may not hold that our patents, if they issue in the future, are valid, enforceable and infringed;

- we may need to initiate litigation or administrative proceedings to enforce and/or defend our patent rights which will be costly whether we win or lose;

- we may choose not to file a patent application in order to maintain certain trade secrets or know-how, and a third party may subsequently file a patent application covering such intellectual property;

- we may fail to adequately protect and police our trademarks and trade secrets; and

- the patents of others may have an adverse effect on our business, including if others obtain patents claiming subject matter similar to or improving that covered by our patent applications.

Should any of these or similar events occur, they could significantly harm our business, financial condition, results of operations and prospects.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope or expiration of a third-party patent, which might adversely affect our ability to develop and market our product candidates.

As the biopharmaceutical industry expands and more patents are issued, the risk increases that our product candidates may be subject to claims of infringement of the patent rights of third parties. There can be no assurance that our operations do not, or will not in the future, infringe, misappropriate or otherwise violate existing or future third-party patents or other intellectual property rights. Identification of third-party patent rights that may be relevant to our operations is difficult because patent searching is imperfect due to differences in terminology among patents, incomplete databases and the difficulty in assessing the meaning of patent claims. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

Numerous United States and foreign patents and pending patent applications exist in our market that are owned by third parties. Our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in patent portfolios and competing technologies, may have applied for or obtained or may in the future apply for and obtain, patents that will prevent, limit or otherwise interfere with our ability to make, use and sell our product candidates. We do not always conduct independent reviews of pending patent applications and patents issued to third parties. Patent applications in the United States and elsewhere are typically published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Certain United States applications that will not be filed outside the United States can remain confidential until patents issue. In addition, patent applications in the United States and elsewhere can be pending for

many years before issuance, or unintentionally abandoned patents or applications can be revived. Furthermore, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use of our product candidates. As such, there may be applications of others now pending or recently revived patents of which we are unaware. These patent applications may later result in issued patents, or the revival of previously abandoned patents, that may be infringed by the manufacture, use or sale of our product candidates or will prevent, limit or otherwise interfere with our ability to make, use or sell our product candidates.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect. For example, we may incorrectly determine that our product candidates are not covered by a third-party patent or may incorrectly predict whether a third-party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market our product candidates.

We cannot provide any assurances that third-party patents and other intellectual property rights do not exist which might be enforced against our current technology, including our research programs, product candidates, their respective methods of use, manufacture and formulations thereof, and could result in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

We may be involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time-consuming and unsuccessful.

Competitors or other third parties may infringe our patents, trademarks or other intellectual property. To counter infringement or unauthorized use, we or any current or future licensors may be required to file infringement claims, which can be expensive and time consuming and divert the time and attention of our management and scientific personnel. Our or any current or future licensors' pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe their patents, in addition to counterclaims asserting that our patents or any current or future licensors' patents are invalid or unenforceable, or both. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non-enablement, insufficient written description or failure to claim patent-eligible subject matter. 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. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In any patent infringement proceeding, there is a risk that a court will decide that a patent of ours or any current or future licensors is invalid or unenforceable, in whole or in part, and that we do not have the right to stop the other party from using the invention at issue. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent's claims narrowly or decide that we do not have the right to stop the other party from using the invention at issue on the grounds that our or any current or future licensors' patent claims do not cover the invention, or decide that the other party's use of our or any current or future licensors' patented technology falls under the safe harbor to patent infringement under 35 U.S.C. §271(e)(1). An adverse outcome in a litigation or proceeding involving our or any current or future licensors' patents could limit our ability to assert our or any current or future licensors' patents against those parties or other competitors and may curtail or preclude our ability to exclude third parties from making and selling similar or competitive products. Any of these occurrences could adversely affect our competitive position, and our business, financial condition, results of operations and prospects. Similarly, if we assert trademark infringement claims, a court may determine that the marks we have asserted are invalid or unenforceable, or that the party against whom we have asserted trademark infringement has superior rights to the marks in question. In this case, we could ultimately be forced to cease use of such trademarks.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. 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 litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could adversely affect the price of shares of our common stock. Moreover, we cannot assure you that we will have sufficient financial or other resources to file and pursue such infringement claims, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

We may become involved in third-party claims of intellectual property infringement, which may prevent or delay our product discovery and development efforts.

Our commercial success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving the infringement of patents and other intellectual property rights in the biotechnology and pharmaceutical industries. We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights and who allege that our product candidates, uses and/or other proprietary technologies infringe their intellectual property rights. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk that our product candidates may give rise to claims of infringement of the patent rights of others increases. Moreover, it is not always clear to industry participants, including us, which patents exist which may be found to cover various types of drugs, products or their methods of use or manufacture. Thus, because of the large number of patents issued and patent applications currently pending in our fields, there may be a risk that third parties may allege they have patent rights which are infringed by our product candidates, technologies or methods.

If a third party alleges that we infringe its intellectual property rights, we may face a number of issues, including, but not limited to:

- infringement and other intellectual property misappropriation which, regardless of merit, may be expensive and time-consuming to litigate and may divert our management's attention from our core business;

- substantial damages for infringement or misappropriation, which we may have to pay if a court decides that the product candidate or technology at issue infringes on or violates the third-party's rights, and, if the court finds we have willfully infringed intellectual property rights, we could be ordered to pay treble damages and the patent owner's attorneys' fees;

- an injunction prohibiting us from manufacturing, marketing or selling our product candidates, or from using our proprietary technologies, unless the third party agrees to license its patent rights to us;

- even if a license is available from a third party, we may have to pay substantial royalties, upfront fees and other amounts, and/or grant cross-licenses to intellectual property rights protecting our products; and

- we may be forced to try to redesign our product candidates or processes so they do not infringe third-party intellectual property rights, an undertaking which may not be possible or which may require substantial monetary expenditures and time.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or could otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

Third parties may assert that we are employing their proprietary technology without authorization. Generally, conducting preclinical and clinical trials and other development activities in the United States is not considered an act of infringement. While we may believe that patent claims or other intellectual property rights of a third party would not have a materially

adverse effect on the commercialization of our product candidates, we may be incorrect in this belief, or we may not be able to prove it in litigation. In this regard, patents issued in the United States by law enjoy a presumption of validity that can be rebutted only with evidence that is "clear and convincing," a heightened standard of proof. There may be issued third-party patents of which we are currently unaware with claims to compositions, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates.

Patent applications can take many years to issue. There may be currently pending patent applications which may later result in issued patents that may be infringed by our product candidates. Moreover, we may fail to identify relevant patents or incorrectly conclude that a patent is invalid, not enforceable, exhausted, or not infringed by our activities. If any third-party patents, held now or obtained in the future by a third party, were found by a court of competent jurisdiction to cover the manufacturing process of our product candidates, the holders of any such patents may be able to block our ability to commercialize the product candidate unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover any aspect of our formulations, any combination therapies or patient selection methods, the holders of any such patent may be able to block our ability to develop and commercialize the product candidate unless we obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If we are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our product candidates, if approved, may be impaired or delayed, which could in turn significantly harm our business. Even if we obtain a license, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future product candidates.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidates. Defense of these claims, regardless of their merit, could involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need or may choose to obtain licenses from third parties to advance our research or allow commercialization of our product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize our product candidates, which could harm our business significantly.

We may not be successful in obtaining or maintaining necessary rights to our product candidates through acquisitions and in-licenses.

Because our development programs may in the future require the use of proprietary rights held by third parties, the growth of our business may depend in part on our ability to acquire, in-license, or use these third-party proprietary rights. We may be unable to acquire or in-license any compositions, methods of use, processes or other third-party intellectual property rights from third parties that we identify as necessary for our product candidates on commercially reasonable terms or at all. Even if we are able to in-license any such necessary intellectual property, it could be on nonexclusive terms, thereby giving our competitors and other third parties access to the same intellectual property licensed to us, and it could require us to make substantial licensing and royalty payments. The licensing and acquisition of third-party intellectual property rights is a competitive area, and a number of more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third-party intellectual property rights or maintain the existing intellectual property rights we have obtained, we may have to abandon development of the relevant program or product candidate, which could adversely affect our business, financial condition, results of operations and prospects.

We may enter into license agreements in the future with others to advance our existing or future research or allow commercialization of our existing or future product candidates, if approved. These licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and product candidates in the future. In that event, we may be required to expend significant time and resources to redesign our product candidates, or the methods for manufacturing them, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected product candidates, if approved, which could harm our business, financial condition, results of operations, and prospects significantly. We cannot provide any assurances that third-party patents do not exist which might be enforced against our current manufacturing methods, product candidates, or future methods or product candidates resulting in either an injunction prohibiting our manufacture or future sales, or, with respect to our future sales, an obligation on our part to pay royalties and/or other forms of compensation to third parties, which could be significant.

We may become subject to claims challenging the inventorship or ownership of our or any current or future licensors' patents and other intellectual property.

We may be subject to claims that former employees, collaborators or other third parties have an interest in our or any current or future licensors' patents or other intellectual property as an inventor or co-inventor. The failure to name the proper inventors on a patent application can result in the patents issuing thereon being unenforceable. Inventorship disputes may arise from conflicting views regarding the contributions of different individuals named as inventors, the effects of foreign laws where foreign nationals are involved in the development of the subject matter of the patent, conflicting obligations of third parties involved in developing our product candidates or as a result of questions regarding co-ownership of potential joint inventions. Litigation may be necessary to resolve these and other claims challenging inventorship or ownership. Alternatively, or additionally, we may enter into agreements to clarify the scope of our rights in such intellectual property. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could adversely affect our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Any current or future licensors may have relied on third-party consultants or collaborators or on funds from third parties, such as the United States government, such that these licensors are not the sole and exclusive owners of the patents we in-licensed. If other third parties have ownership rights or other rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technology. This could adversely affect our competitive position, business, financial condition, results of operations and prospects.

In addition, while it is our policy to require our employees and contractors who may be involved in the conception or 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, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self-executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could adversely affect our business, financial condition, results of operations and prospects.

We have and may continue to form or seek collaborations or strategic alliances or enter into licensing arrangements in the future, and we may neither enter into, nor realize the benefits of, such alliances or licensing arrangements.

The current, and any future, collaborations that we enter into may not be successful and we may not enter into such collaborations at all. The success of our collaboration arrangements will depend heavily on the efforts and activities of any future collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;

- collaborators may not pursue development and commercialization of our product candidates or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their

strategic focus due to the acquisition of competitive products, availability of funding or other external factors, such as a business combination that diverts resources or creates competing priorities;

- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates;

- a collaborator with marketing, manufacturing and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;

- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or proprietary information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to potential liability;

- disputes may arise between us and a collaborator that causes the delay or termination of the research, development or commercialization of our future product candidates or that results in costly litigation or arbitration that diverts management attention and resources;

- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable future product candidates;

- collaborators may own or co-own intellectual property covering our product candidates that results from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and

- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

If we fail to comply with our obligations in the agreements under which we in-license or acquire development or commercialization rights to product candidates, or data from third parties, we could lose such rights that are important to our business.

We are heavily reliant upon licenses to certain patent rights and other intellectual property for the development of lonigutamab. For example, we depend on licenses from Pierre Fabre for certain intellectual property relating to the development and commercialization of lonigutamab, respectively, in specific territories.

Pierre Fabre may have relied upon, and any future licensors may rely upon, third-party companies, consultants or collaborators, or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-licensed. If our licensors, including Pierre Fabre, fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize lonigutamab could be adversely affected. Further development and commercialization of lonigutamab and development of any other future product candidates may require us to enter into additional license or collaboration agreements. For example, our licensors or other third parties may develop intellectual property covering lonigutamab which we have not licensed. Our future licenses may not provide us with exclusive rights to use the licensed patent rights and other intellectual property licensed thereunder, or may not provide us with exclusive rights to use such patent rights and intellectual property in all relevant fields of use and in all territories in which we wish to develop or commercialize lonigutamab or our other product candidates in the future.

In spite of our efforts, licensors such as Pierre Fabre might conclude that we are in material breach of obligations under our license agreements and may therefore have the right to terminate the license agreements, thereby removing our ability to develop and commercialize product candidates and technology covered by such license agreements. If such in-licenses are terminated, or if the underlying patents fail to provide the intended exclusivity, our competitors would have the freedom

to seek regulatory approval of, and to market, products identical to our product candidates and the licensors to such in-licenses could prevent us from developing or commercializing product candidates that rely upon the patents or other intellectual property rights which were the subject matter of such terminated agreements. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses and compete with our existing product candidates. Any of these events could adversely affect our business, financial condition, results of operations, and prospects.

Disputes may arise regarding intellectual property subject to a licensing agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- our financial or other obligations under the license agreement;
- the extent to which our processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights under our collaborative development relationships;
- our diligence obligations under the license agreement and what activities satisfy those obligations;
- the inventorship or ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners; and
- the priority of invention of patented technology.

In addition, our license agreements are, and any future license agreements are likely to be, complex, and certain provisions in such agreements may be susceptible to multiple interpretations.

The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or increase what we believe to be our financial or other obligations under the relevant agreement, either of which could adversely affect our business, financial condition, results of operations, and prospects. Moreover, if disputes over intellectual property that we have licensed or may license in the future prevent or impair our ability to maintain our current or future licensing arrangements on commercially acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates, which could adversely affect our business, financial condition, results of operations, and prospects.

We have entered into, and may in the future enter into, license agreements that subject us to certain rights retained by third parties.

We have entered into a regional collaboration and license agreement (the "Kaken Collaboration Agreement") with Kaken Pharmaceutical Co., Ltd. ("Kaken") pursuant to which we have granted Kaken an exclusive license to develop, manufacture and commercialize envu for dermatology indications in Japan. Under the Kaken Collaboration Agreement, Kaken has options to expand the license into rheumatological and gastrointestinal indications in Japan, and Kaken is responsible for the clinical development, regulatory approvals and commercialization of envu in Japan in dermatology and other indications for which Kaken has exercised its option. We retain global rights to envu outside of those granted to Kaken. In addition, any future licensors may retain certain rights under the relevant agreements with us, including the right to use the underlying product candidates for academic and research use, to publish general scientific findings from research related to the product candidates, to make customary scientific and scholarly disclosures of information relating to the product candidates, or to develop or commercialize the licensed product candidates in certain regions.

In addition, the United States federal government retains certain rights in inventions produced with its financial assistance

under the Patent and Trademark Law Amendments Act (the "Bayh-Dole Act"). The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. We may at times choose to collaborate with academic institutions to accelerate our preclinical research or development. While we do not currently engage, and it is our policy to avoid engaging, university partners in projects in which there is a risk that federal funds may be commingled, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be adversely affected.

Changes in patent law in the United States and other jurisdictions could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other biopharmaceutical companies, our success is heavily dependent on intellectual property, particularly patents. Obtaining, defending, maintaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity and is therefore costly, time consuming and inherently uncertain. Changes in either the patent laws or interpretation of the patent laws in the United States could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents, and may diminish our ability to protect our inventions, obtain, maintain, enforce and protect our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our future owned and licensed patents. Patent reform legislation in the United States and other countries, including the Leahy-Smith America Invents Act (the "Leahy-Smith Act"), signed into law on September 16, 2011, could increase those uncertainties and costs surrounding the prosecution of patent applications filed after March 2013 and the enforcement or defense of our future issued patents or claiming priority to patent applications filed after March 2013. The Leahy-Smith Act includes a number of significant changes to United States patent law. These include provisions that affect the way patent applications are prosecuted, redefine prior art and provide more efficient and cost-effective avenues for competitors to challenge the validity of patents. These include allowing third-party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post-grant proceedings, including PGR, IPR, and derivation proceedings.

Further, because of a lower evidentiary standard in these USPTO post-grant proceedings compared to the evidentiary standard in United States federal courts necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid even though the same evidence would be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our or any current or future licensors' patent claims that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Thus, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our or any current or future licensors' patent applications and the enforcement or defense of our or any current or future licensors' future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

After March 2013, under the Leahy-Smith Act, the United States transitioned to a first inventor to file system in which, assuming that the other statutory requirements are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third-party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before we file an application covering the same invention, could therefore be awarded a patent covering an invention of ours or any current or future licensors even if we had made the invention before it was made by such third party. This will require us to be cognizant going forward of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or any current or future licensors were the first to either (i) file any patent application related to our product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our or any current or future licensors' patents or patent applications. Even where we have a valid and enforceable patent, we may not be able to exclude others from practicing the claimed invention where the other party can show that they used the invention in commerce before our filing date or

the other party benefits from a compulsory license. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our future issued patents, all of which could adversely affect our business, financial condition, results of operations and prospects.

In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. The United States Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. Depending on future actions by the United States Congress, the United States courts, the USPTO and the relevant law-making bodies in other countries, the laws and regulations governing patents could change in unpredictable ways that would weaken our or any current or future licensors' ability to obtain new patents and patents that we or any current or future licensors might obtain in the future. We cannot predict how future decisions by the courts, the United States Congress or the USPTO may impact the value of our patents. Any similar adverse change in the patent laws of other jurisdictions could also adversely affect our business, financial condition, results of operations and prospects.

In 2012, the European Union Patent Package ("EU Patent Package") regulations were passed with the goal of providing a single pan-European Unitary Patent and a new European Unified Patent Court ("UPC") for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC's existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt-out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents and allow for the possibility of a competitor to obtain pan-European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and product candidates and, resultantly, on our business, financial condition, prospects and results of operations.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated as a result of noncompliance with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on patents and/or applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and patent applications. We rely on our outside patent counsel to pay these fees due to United States and non-United States patent agencies. The USPTO and various non-United States government patent agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In many cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market and this circumstance could adversely affect our business, financial condition, results of operations and prospects.

Patent terms may be inadequate to protect our competitive position on products or product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest United States non-provisional or international patent application filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our products or product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including generics or biosimilars. Given the amount of time required for the development, testing and regulatory review of products or new product candidates, patents protecting such products or candidates might

expire before or shortly after such products or candidates are commercialized. As a result, our patent portfolio may not provide us with sufficient and continuing rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension for our product candidates, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA regulatory approval of our product candidates, one or more of our issued United States patents or issued United States patents that we may own in the future may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 (the "Hatch-Waxman Amendments"). The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it or a method for manufacturing it may be extended. Similar patent term restoration provisions to compensate for commercialization delay caused by regulatory review are also available in certain foreign jurisdictions, such as in Europe under SPC. However, we may not be granted any extensions for which we apply because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. In addition, to the extent we wish to pursue patent term extension based on a patent that we in-license from a third party, we would need the cooperation of that third party. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension, or the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to the protection afforded by patents, we seek to rely on trade secret protection to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information, or technology that is not covered by our patents. We may not be able to meaningfully protect our trade secrets. Although we require all of our employees to assign their inventions to us, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information, or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed to our competitors or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws within the United States. We may need to share our trade secrets and proprietary know-how with current or future partners, collaborators, contractors and others located in countries at heightened risk of theft of trade secrets, including through direct intrusion by private parties or foreign actors, and those affiliated with or controlled by state actors. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Monitoring and detecting unauthorized disclosure or other compromise of trade secrets is difficult, and we do not know whether the steps we have taken to prevent such compromise are, or will be, adequate. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time-consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. If we choose to go to court to stop a third party from using any of our trade secrets, we may incur substantial costs. These lawsuits may consume our time and other resources even if we are successful. For example, significant elements of our business, including confidential aspects of sample preparation, methods of manufacturing, proprietary assays, computational-biological algorithms, data analytics and machine learning related to genetics, genomics, proteomics, biomarkers and samples, and related processes and software, are based on unpatented trade secrets, including those of our collaborators. For example, our collaborator, Foresite Labs, utilizes extensive trade secret algorithms, machine learning

and AI analysis techniques, and we rely on their maintenance of these trade secrets. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology.

We may be subject to claims asserting that our employees, consultants or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property.

Certain of our employees, consultants or advisors have in the past and may in the future be employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that these individuals or we have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights. An inability to incorporate such technologies or features would harm our business and may prevent us from successfully commercializing our technologies or product candidates. In addition, we may lose personnel as a result of such claims and any such litigation, or the threat thereof, may adversely affect our ability to hire employees or contract with independent contractors. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our technologies, or product candidates, which could adversely affect our business, financial condition, results of operations and prospects. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

In addition, we may in the future be subject to claims by former employees, consultants or other third parties asserting an ownership right in our patents or patent applications. An adverse determination in any such submission or proceeding 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 our ability to stop others from using or commercializing similar technology and therapeutics, without payment to us, or could limit the duration of the patent protection covering our technologies and product candidates. Such challenges may also result in our inability to develop, manufacture or commercialize our technologies and product candidates without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to license, develop or commercialize current or future technologies and product candidates. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our unregistered trademarks, trade names or future registered trademarks may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we have proposed to use with our product candidate in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark.

We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition

among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively, and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, domain name or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Government Regulation

Even if we receive regulatory approval for our product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, could be subject to labeling and other restrictions and market withdrawal. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with our product candidates.

Any regulatory approvals that we or our future collaborators obtain for our product candidates may also be subject to limitations on the approved indicated uses for which a product may be marketed or to the conditions of approval, or contain requirements for potentially costly post-marketing testing and surveillance to monitor the safety and efficacy of the product candidate.

In addition, if the FDA or a comparable foreign regulatory authority approves our product candidates, the manufacturing processes, labeling, packaging, distribution, post-approval monitoring and AE reporting, storage, import, export, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. The FDA has significant post-market authority, including the authority to require labeling changes based on new safety information and to require post-market studies or clinical trials to evaluate safety risks related to the use of a product or to require withdrawal of the product from the market. The FDA also has the authority to require a REMS after approval, which may impose further requirements or restrictions on the distribution or use of an approved drug. Comparable foreign regulatory authorities may have similar authority. The manufacturing facilities we use to make a future product, if any, will also be subject to periodic review and inspection by the FDA and other regulatory authorities, including for continued compliance with cGMP requirements. The discovery of any new or previously unknown problems with our third-party manufacturers, manufacturing processes or facilities may result in restrictions on the product, manufacturer or facility, including withdrawal of the product from the market. As we expect to rely on third-party manufacturers, we will have limited control over compliance with applicable rules and regulations by such manufacturers.

In addition, any product promotion and advertising will also be subject to regulatory requirements and continuing regulatory review. For example, the FDA and comparable foreign regulatory authorities impose stringent restrictions on manufacturers' communications regarding use of their products. Although clinicians may prescribe products for off-label uses, as the FDA and comparable foreign regulatory authorities do not regulate a physician's choice of drug treatment made in the physician's independent medical judgment, the FDA and such comparable foreign regulatory authorities do restrict promotional communications from companies or their sales force with respect to off-label uses of products. Specifically, any regulatory approval that the FDA grants is limited to those specific diseases and indications for which a product is deemed to be safe and effective by FDA, and our ability to promote any products will be narrowly limited to those indications that are specifically approved by the FDA. Similar restrictions apply in other countries. In the EU, applicable laws require that promotional materials and advertising in relation to medicinal products comply with the product's Summary of Product Characteristics ("SmPC") which may require approval by the competent national authorities in connection with a marketing authorization. The SmPC is the document that provides information to physicians concerning the safe and effective use of the product. Promotional activity that does not comply with the SmPC is considered off-label and is prohibited in the EU. If we are found to have promoted such off-label uses, we may become subject to significant liability. In addition, if we do not conduct head-to-head comparative clinical trials for our product candidates, we will be unable to make comparative claims regarding any other products in the promotional materials for our product candidates. If we promote our products, if approved, in a manner inconsistent with FDA-approved labeling,

or the labeling approved by another comparable foreign regulatory authority, or otherwise not in compliance with FDA regulations or comparable foreign rules, we may be subject to enforcement action. The U.S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and has enjoined several companies from engaging in off-label promotion. The FDA has also requested that companies enter into consent decrees or permanent injunctions under which specified promotional conduct is changed or curtailed.

Subsequent discovery of previously unknown problems with a product, including AEs of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure by us, our contract manufacturers or service providers, or collaborators to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls;
- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- operating restrictions;
- holds on clinical trials;
- warning or untitled letters;
- refusal by the FDA or comparable foreign regulatory authorities to approve, or delays in the approval of, pending applications or supplements to approved applications;
- suspension, variation or revocation of product approvals;
- product seizure or detention or refusal to permit the import or export of products; and
- injunctions, or the imposition of civil or criminal penalties.

The occurrence of any event or penalty described above may inhibit our ability to commercialize our product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity.

The FDA's and comparable foreign regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of any product candidates we develop. We also cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. In addition, the U.S. Supreme Court's July 2024 decision to overturn established case law giving deference to regulatory agencies' interpretations of ambiguous statutory language has introduced uncertainty regarding the extent to which the FDA's regulations, policies and decisions may become subject to increasing legal challenges, delays, and/or changes. As a result of the U.S. Supreme Court's decision, the FDA and other agencies may be less inclined to engage in formal regulation and may rely to a greater degree on informal guidance, which may not always be susceptible to immediate challenge. We cannot predict the likelihood, nature or extent of government regulation or guidance that may arise from future court decisions, legislation, or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

Recently enacted legislation, future legislation and other healthcare reform measures may increase the difficulty and cost for us to obtain regulatory approval for and commercialize our product candidates and may affect the prices we may set.

In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of

legislative and regulatory changes to the healthcare system, including cost-containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell any product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U.S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare.

For example, in March 2010, the ACA was enacted in the United States, which made a number of substantial changes in the way healthcare is financed by both governmental and private insurers. Since its enactment, there have been amendments and judicial, Congressional and executive branch challenges to certain aspects of the ACA. For example, on July 4, 2025, the OBBBA was signed into law, which narrowed access to ACA marketplace exchange enrollment and declined to extend the ACA 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 ACA 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 or additional pricing pressures.

The current administration is pursuing policies to reduce regulations and expenditures across government agencies including at HHS, the FDA, the 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 establishing Most-Favored-Nation pricing for pharmaceutical products and launching an online clearinghouse, referred to as TrumpRx, for patients to purchase certain products from manufacturers on a cash pay basis; (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, the U.S. Supreme Court's Loper Bright decision greatly reduced judicial deference to regulatory agencies, which could increase successful legal challenges to federal regulations affecting our operations. Congress may introduce and ultimately pass health care related legislation that could, among other things, 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 expect that these and any other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. 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 healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates, if approved.

Moreover, in order to obtain reimbursement for our products in some European countries, including some EU member states, we may be required to compile additional data comparing the cost-effectiveness of our products to other available therapies. This assessment of medicinal products is becoming an increasingly common part of the pricing and reimbursement procedures in some EU member states, including those representing the larger markets. The HTA process is the procedure to assess therapeutic, economic and societal impact of a given medicinal product in the national healthcare systems of the original country. The outcome of an HTA will often influence the pricing and reimbursement status granted to these medicinal products by the competent authorities of individual EU member states. The extent to which pricing and reimbursement decisions are influenced by the HTA of the specific medicinal product currently varies between EU member states. On January 12, 2025, Regulation No 2021/2282 on HTA amending Directive 2011/24/EU, entered into force through a phased implementation depending on the concerned products. The Regulation intends to boost cooperation among EU member states in assessing health technologies, including new medicinal products. The Regulation establishes the framework for EU level joint clinical assessments, joint clinical assessments, joint scientific consultations, and the early identification of emerging health technologies. It permits EU member states to use common HTA tools, methodologies, and procedures across the EU, working together in four main areas and requires them to rely on EU-level joint clinical assessment reports for the clinical components of their national HTA evaluations. Individual EU member states will continue to be responsible for assessing non-clinical (e.g., economic, social, ethical) aspects of health technologies and making decisions on pricing and reimbursement. If we are unable to maintain favorable pricing and reimbursement status in EU member states for product candidates that we may successfully develop and for which we may obtain regulatory approval, any anticipated revenue from and growth prospects for those products in the EU could be negatively affected.

Our operations and relationships with healthcare providers, healthcare organizations and third-party payors will be subject to applicable anti-bribery, anti-kickback, fraud and abuse, transparency and other healthcare laws and regulations, which could expose us to, among other things, enforcement actions, criminal sanctions, civil penalties, contractual damages, reputational harm, administrative burdens and diminished profits and future earnings.

Our arrangements with healthcare providers, healthcare organizations and third-party payors will expose us to broadly applicable anti-bribery, fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we research, market, sell and distribute our product candidates, if approved. Restrictions under applicable federal, state and foreign anti-bribery and healthcare laws and regulations, include the following:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals 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, in whole or in part, under a federal and state healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- the federal criminal and civil false claims laws, including the federal False Claims Act, which can be enforced through civil whistleblower or qui tam actions against individuals or entities, and the Federal Civil Monetary Penalties Laws, which prohibit, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, certain marketing practices, including off-label promotion, may also violate false claims laws. Moreover, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act;

- HIPAA, which imposes criminal and civil liability, prohibits, among other things, knowingly and willfully

executing, or attempting to execute a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services; 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 in order to have committed a violation;

- HIPAA, as amended by HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information;

- the federal legislation commonly referred to as the Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, which requires certain manufacturers of covered drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid, or the Children's Health Insurance Program, with certain exceptions, to report annually to CMS information on certain payments and other transfers of value to clinicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), teaching hospitals, and certain other health care providers (such as physician assistants and nurse practitioners), as well as ownership and investment interests held by the clinicians described above and their immediate family members;

- the U.S. Foreign Corrupt Practices Act of 1977, as amended, which prohibits, among other things, U.S. companies and their employees and agents from authorizing, promising, offering, or providing, directly or indirectly, corrupt or improper payments or anything else of value to foreign government officials, employees of public international organizations and foreign government owned or affiliated entities, candidates for foreign political office, and foreign political parties or officials thereof;

- analogous state and foreign laws and regulations, such as state and foreign anti-kickback and false claims laws, that may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; and

- certain 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 government in addition to requiring drug manufacturers to report information related to payments to clinicians and other healthcare providers or marketing expenditures and drug pricing information, and state and local laws that require the registration of pharmaceutical sales representatives.

In the EU, interactions between pharmaceutical companies and healthcare professionals and healthcare organizations are governed by strict laws, regulations, industry self-regulation codes of conduct and physicians' codes of professional conduct both at EU level and in the individual EU member states. The provision of benefits or advantages to healthcare professionals to induce or encourage the prescription, recommendation, endorsement, purchase, supply, order or use of pharmaceutical products is prohibited in the EU. Relationships with healthcare professionals and associations are subject to stringent anti-gift statutes and anti-bribery laws, the scope of which differs across the EU. In addition, national transparency and reporting rules may require pharmaceutical companies to report/publish transfers of value provided to healthcare professionals and associations on a regular (e.g. annual) basis.

If we or our future collaborators, manufacturers or service providers fail to comply with applicable federal, state or foreign laws or regulations, we could be subject to enforcement actions, which could affect our ability to develop, market and sell our product candidates successfully and could harm our reputation and lead to reduced acceptance of our products, if approved by the market.

Efforts to ensure that our current and future business arrangements with third parties comply with applicable healthcare laws and regulations could involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any such requirements, we may be subject to significant penalties, including civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, the curtailment or restructuring of our operations, loss of eligibility to obtain

approvals from the FDA or comparable foreign regulatory authorities, exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid or comparable foreign programs, integrity oversight and reporting obligations, or reputational harm, any of which could adversely affect our financial results. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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

In some countries, particularly in the EU, 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 regulatory approval for a drug. To obtain coverage and reimbursement or pricing approval in some countries, we may be required to conduct a study that compares the cost-effectiveness of our product candidate to other available therapies. In addition, many countries outside the United States have limited government support programs that provide for reimbursement of drugs such as our product candidates, with an emphasis on private payors for access to commercial products. If reimbursement of our products, if approved, is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be materially harmed.

We and the third parties with whom we work are subject to stringent and evolving U.S. and foreign laws, regulations, rules; contractual obligations; policies; and other obligations related to data privacy and security. Our (including the third parties with whom we work) actual or perceived failure to comply with such obligations could lead 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 for our business, results of operations and financial condition.

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 or processing) personal information and other sensitive information, including proprietary and confidential business data, trade secrets, employee data, intellectual property, data we collect about trial participants in connection with clinical trials, and other sensitive third-party data (collectively, sensitive information). Our data processing activities presently and may in the future 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.

Various federal, state, local and foreign legislative and regulatory bodies, or self-regulatory organizations, may expand current laws, rules or regulations, enact new laws, rules or regulations or issue revised rules or guidance regarding data privacy and security. Implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future, and we cannot yet determine the impact future laws, regulations, standards, or perception of their requirements may have on our business.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws, including data breach notification laws, personal information privacy laws, and consumer protection laws. For example, HIPAA imposes specific requirements relating to the privacy, security, and transmission of individually identifiable health information. We may obtain health information from third parties that are subject to privacy and security requirements under HIPAA. Depending on the facts and circumstances, we could be subject to significant penalties if we violate HIPAA.

Additionally, the CCPA applies to personal information of California consumers, business representatives, and employees, and among other things requires regulated businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights, including the right to opt out of certain disclosures of their information. The CCPA provides for civil penalties as well as a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. In addition, although the CCPA includes limited exceptions, including for certain information collected as part of clinical trials, the CCPA may impact our processing of personal data and our compliance costs depending on how it is interpreted. Similar laws are being considered

or have been enacted in several other states, as well as at the federal and local levels. While certain U.S. state privacy laws, like the CCPA, may also exempt some data processed in the context of clinical trials, these developments further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties with whom we work. In addition to government activity, privacy advocacy groups and technology and other industries are considering various new, additional or different self-regulatory standards that may place additional burdens on us.

There are also various laws, regulations and industry standards in other jurisdictions outside the United States relating to data privacy and security, with which we presently or in the future may need to comply. For example, the EU's General Data Protection Regulation ("EU GDPR") and the UK's equivalent ("UK GDPR"), collectively, GDPR, impose strict requirements for processing personal information (referred to as "personal data" under the GDPR). Notably, under the GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to €20 million under the EU GDPR / £17.5 million under the UK GDPR, or, in each case, 4% of the annual global revenue of the noncompliant undertaking, whichever is greater. The GDPR also provides for 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. Additionally, EU member states may introduce further conditions, including limitations, and make their own laws and regulations further limiting the processing of "special categories of personal data," including personal data related to health, biometric data used for unique identification purposes and genetic information, which could limit our ability to process such special categories of personal data, and could cause our compliance costs to increase, ultimately adversely affecting our business, financial condition, results of operations and prospects.

Certain of our employees, other personnel and/or vendors use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Any errors, flaws or other unintended issues in or associated with AI inputs, outputs or technologies could result in adverse impacts on our business. Governments have passed and are likely to pass additional laws regulating generative AI. Our, or our vendors', use of this technology could result in additional compliance costs, regulatory investigations and actions, and lawsuits. If we, or our vendors, are unable to use generative AI, it could make our business less efficient in some cases, and result in increased costs or competitive disadvantages.

In addition, we may be unable to transfer personal information 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 information to other countries. In particular, the European Economic Area (the "EEA") and the UK have significantly restricted the transfer of personal information to the United States and other countries whose privacy laws it generally believes are inadequate. Although there are currently various mechanisms that may be used to transfer personal information from the EEA and UK to the United States in compliance with law, such as the EEA standard contractual clauses, the UK's International Data Transfer Agreement / Addendum, the EU-US Data Privacy Framework, and the UK extension thereto ("Data Privacy Framework") (which allows for transfers to relevant U.S.-based organizations who self-certify compliance and participate in the Data Privacy 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 information to the United States.

Other jurisdictions may adopt or have already adopted similarly stringent data localization and cross-border data transfer laws. If there is no lawful manner for us to transfer personal information 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 business or data processing activities to other jurisdictions 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 information necessary to operate our business. Additionally, companies that transfer personal information 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 out of Europe for allegedly violating the GDPR's cross-border data transfer limitations. Regulators in the United States are also increasingly scrutinizing certain personal information transfers and have enacted certain restrictions on cross-border date transfers. For example, 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, Russia, Iran) 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 impacts certain business activities such as vendor engagements, sale or sharing of data, employment of certain individuals, and investor agreements. Violations of the rule could lead to significant civil and criminal fines and penalties. The rule applies regardless of whether data is anonymized, key-coded, pseudonymized, de-identified or encrypted, which presents particular challenges for companies like ours that process key-coded clinical trial data and biospecimens.

In addition to data privacy and security laws, 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.

Each of these laws, rules, regulations and contractual obligations relating to data privacy and security, and any other such changes or new laws, rules, regulations or contractual obligations could impose significant limitations, require changes to our business, or restrict our collection, use, storage or processing of personal information, which may increase our compliance expenses and make our business more costly or less efficient to conduct. In addition, any such changes could compromise our ability to develop an adequate marketing strategy and pursue our growth strategy effectively or even prevent us from providing certain products in jurisdictions in which we currently operate and in which we may operate in the future or incur potential liability in an effort to comply with such legislation, which, in turn, could adversely affect our business, financial condition, results of operations and prospects. Complying with these numerous, complex and often changing regulations is expensive and difficult, and failure to comply with any data privacy or security obligations, whether by us, one of our CROs, CMOs or another third party with whom we work, could adversely affect our business, financial condition, results of operations and prospects, including but not limited to: regulatory investigation costs; material fines and penalties; compensatory, special, punitive and statutory damages; litigation (including class claims); consent orders regarding our data privacy and security practices; requirements that we provide notices, bans on processing personal information (including clinical trial data), orders to destroy or not use personal information, credit monitoring services and/or credit restoration services or other relevant services to impacted individuals in the event of an information security incident impacting personal information; adverse actions against our licenses to do business; reputational damage; and injunctive relief. The implementation of the GDPR has increased our responsibility and liability in relation to sensitive information that we process, including in clinical trials, that is subject to the GDPR, and we may be required to put in place additional mechanisms to comply with the GDPR and other applicable laws and regulations, which could divert management's attention and increase our cost of doing business. In addition, new regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase our costs of doing business. For instance, in Europe, the second Network and Information Security Directive ("NIS2") aims to improve the resilience and incident response capabilities of entities operating in a number of sectors, including the health sector. Non-compliance with NIS2, as applicable to us, may lead to administrative fines of a maximum of €10 million or up to 2% of the total worldwide turnover of the preceding financial year. In this regard, we expect that there will continue to be new proposed laws, regulations and industry standards relating to privacy, data protection and security in the United States, the EEA, the UK and other jurisdictions, and we cannot determine the impact such future laws, regulations and standards may have on our business.

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. Any actual or perceived failure by us or third parties with whom we work to comply with any federal, state or foreign laws, rules, regulations, industry self-regulatory principles, industry standards or codes of conduct, regulatory guidance, orders to which we (or third parties with whom we work) may be subject or other legal obligations relating to privacy, data protection, data security or consumer protection could adversely affect our reputation, brand and business. We may also be contractually required to indemnify and hold harmless third parties from the costs or consequences of non-compliance with any laws, rules and regulations or other legal obligations relating to privacy or any inadvertent or unauthorized use or disclosure, or other compromise of data that we store or handle as part of operating our business. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: interruptions or stoppages in our business operations (including clinical trials and the development of product candidates); inability to process personal information or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations. 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 monumental statutory damages, depending on the volume of data and the number of violations.

We cannot assure you that our CROs, CMOs or other third-party service providers with access to our or our suppliers', manufacturers', trial participants', employees' and others' sensitive information in relation to which we are responsible will not breach contractual obligations imposed by us, or that they will not experience data security incidents, which could have a corresponding effect on our business, including putting us in breach of our obligations including under privacy laws and regulations and/or which could in turn adversely affect our business, financial condition, results of operations and prospects. We cannot assure you that our contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing of such information. Any of the foregoing could adversely affect our business, financial condition, results of operations and prospects.

We also publicly post privacy policies, marketing materials, whitepapers, and other statements concerning data privacy, security, and our collection, use, disclosure and other processing of the personal information provided to us or that we collect. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be perceived to have failed to do so. Regulators in the United States and elsewhere are increasingly scrutinizing these statements, and our publication of our privacy policies and other statements we publish that provide promises and assurances about data privacy and security can subject us to potential claims if they are found to be deceptive, unfair, misleading, or misrepresentative of our actual practices. Any actual or perceived failure by us to comply with federal, state or foreign laws, rules or regulations, industry standards, contractual or other legal obligations, or any actual, perceived or suspected cybersecurity incident, whether or not resulting in unauthorized access to, or acquisition, release, transfer or other compromise of personal information or other sensitive information, may result in enforcement actions and prosecutions, private litigation (including class action claims), significant fines, penalties (including bans on processing personal information or orders to destroy or not use personal information) and censure, claims for damages by affected individuals, regulatory inquiries and investigations or adverse publicity and could cause reputational harm, any of which could adversely affect our business, financial condition, results of operations and prospects. The successful assertion of one or more large data privacy or security claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

Risks Related to Our Reliance on Third Parties

We may have conflicts with any current or future licensors, licensees, collaborators or strategic partners that could delay or prevent the development or commercialization of our product candidates.

We are currently party to the Kaken Collaboration Agreement and the license and collaboration agreement with Pierre Fabre, and we may enter into strategic transactions in the future, and we may have conflicts with our current or future licensors, licensees, collaborators or strategic partners, such as conflicts concerning the interpretation of preclinical or clinical data, the achievement of milestones, the interpretation of contractual obligations, payments for services, development obligations or the ownership of intellectual property developed during our collaboration. If any conflicts arise with our collaborators, such collaborator may act in a manner that is adverse to our best interests. Any such disagreement could result in one or more of the following, each of which could delay or prevent the development or commercialization of our product candidates, and in turn prevent us from generating revenue: disputes regarding milestone payments or royalties; uncertainty regarding ownership of intellectual property rights arising from our collaborative activities, which could prevent us from entering into future additional collaborations; unwillingness by such collaborator to cooperate in the development or manufacture of a product candidate, including providing us with data or materials; unwillingness on the part of a collaborator to keep us informed regarding the progress of its development and commercialization activities or to permit public disclosure of the results of those activities; initiating of litigation or alternative dispute resolution options by either party to resolve the dispute; or attempts by either party to terminate the agreement.

We have relied and expect to continue to rely on third parties to conduct our preclinical studies and clinical trials. If those third parties do not perform as contractually required, fail to satisfy legal or regulatory requirements, miss expected deadlines or terminate the relationship, our development programs could be delayed, more costly or unsuccessful, and we may never be able to seek or obtain regulatory approval for or commercialize our product candidates.

We rely and intend to rely in the future on third-party clinical investigators, CROs and clinical data management organizations to conduct, supervise and monitor preclinical studies and clinical trials of our current or future product candidates. Because we currently rely and intend to continue to rely on these third parties, we will have less control over the timing, quality and other aspects of preclinical studies and clinical trials than we would have if we had conducted them independently. These parties are not, and will not be, our employees and we will have limited control over the amount of time and resources that they dedicate to our programs. Additionally, such parties may have contractual relationships with other entities, some of which may be our competitors, which may draw time and resources from our programs.

We have no experience as a company in submitting and supporting the applications necessary to gain regulatory approvals. Securing regulatory approval requires the submission of extensive preclinical and clinical data and supporting information to regulatory authorities for each indication to establish the product candidate's safety or efficacy for that indication. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities and clinical trial sites by, applicable regulatory authorities.

Large-scale clinical trials require significant financial and management resources, and reliance on third-party clinical investigators, CROs, partners or consultants. Relying on third-party clinical investigators or CROs may force us to encounter delays and challenges that are outside of our control. We may not be able to demonstrate sufficient comparability between products manufactured at different facilities to allow for inclusion of the clinical results from participants treated with products from these different facilities, in our product registrations. Further, our third-party clinical manufacturers may not be able to manufacture our product candidates or otherwise fulfill their obligations to us because of interruptions to their business, including the loss of their key staff or interruptions to their raw material supply.

Our reliance on these third parties for development activities will reduce our control over these activities. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable trial protocol and legal, regulatory and scientific standards, and our reliance on the CROs, clinical trial sites, and other third parties does not relieve us of these responsibilities. For example, we will remain responsible for ensuring that each of our preclinical studies are conducted in accordance with good laboratory practices, where applicable, and clinical trials are conducted in accordance with GCPs and applicable rules. Moreover, the FDA and comparable foreign regulatory authorities require us to comply with GCP 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. Regulatory authorities enforce these requirements through periodic inspections (including through inspections that may be conducted once we submit an NDA to the FDA) of trial sponsors, clinical investigators, trial sites and certain third parties including CROs. If we, our CROs, clinical trial sites, or other third parties fail to comply with applicable GCP or other regulatory requirements, we or they may be subject to enforcement or other legal actions, 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. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials comply with GCP regulations. Moreover, our business may be significantly impacted if our CROs, clinical investigators or other third parties violate federal or state healthcare fraud and abuse or false claims laws and regulations or healthcare privacy and security laws, and foreign equivalents.

In the event we need to repeat, extend, delay or terminate our clinical trials because these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct our clinical trials in accordance with regulatory requirements or our stated protocols, our clinical trials may need to be repeated, extended, delayed or terminated and we may not be able to obtain, or may be delayed in obtaining, regulatory approvals for our product candidates, and we will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates or we or they may be subject to regulatory enforcement actions. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. To the extent we are unable to successfully identify and manage the performance of third-party service providers in the future,

our business may be materially and adversely affected.

If any of our relationships with these third parties terminate, we may not be able to enter into alternative arrangements or do so on commercially reasonable terms. Switching or adding additional contractors involves additional cost and time and requires management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays could occur, which could compromise our ability to meet our desired development timelines. In addition, if an agreement with any of our future collaborators terminates, our access to technology and intellectual property licensed to us by that collaborator may be restricted or terminate entirely, which may delay our continued development of our product candidates utilizing the collaborator's technology or intellectual property or require us to stop development of those product candidates completely.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authorities may conclude that a financial relationship between us and/or a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authorities and may ultimately lead to the denial of regulatory approval of one or more of our product candidates.

We rely on third-party manufacturers and suppliers to supply our product candidates. The loss of our third-party manufacturers or suppliers, or their failure to comply with applicable regulatory requirements or to supply sufficient quantities at acceptable quality levels or prices, within acceptable timeframes, or at all, would materially and adversely affect our business.

We do not own or operate, and currently have no plans to establish, any manufacturing facilities for drug manufacturing, storage, distribution or quality testing. We currently rely, and expect to continue to rely, on third parties for the manufacture of API, bulk drug substances, raw materials, samples, components and other materials for our product candidates for clinical testing, as well as for the manufacture of any products candidates that we commercialize, if approved. Reliance on third-party manufacturers may expose us to different risks than if we were to manufacture product candidates ourselves. There can be no assurance that our preclinical and clinical development product supplies will not be limited, interrupted, terminated or will be of satisfactory quality or be available at acceptable prices. In addition, if any biotechnology companies or CMOs become subject to trade restrictions, sanctions, or other regulatory requirements by the U.S. government, such actions could restrict or even prohibit our ability to work with such entities. Such disruption could have adverse effects on the development of our product candidates and our business operations. Also, any replacement of our manufacturer could require significant effort and time because there may be a limited number of qualified replacements.

We obtain our preclinical and clinical supplies from our manufacturers on a purchase order basis, and currently do not have long-term supply arrangements in place. The manufacturing process for our product candidates is subject to the FDA and foreign regulatory authority review. We, and our suppliers and manufacturers, must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by regulatory authorities in order to comply with regulatory standards, such as cGMPs. If our CMOs cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or comparable foreign regulatory authorities, we may not be able to rely on their facilities for the manufacture of elements of our product candidates. Securing regulatory approval also requires the submission of information about the product manufacturing process to, and inspection of manufacturing facilities by, the FDA, and comparable foreign regulatory authorities. If the FDA or any comparable foreign regulatory authority determines that our third-party manufacturers' facilities are not in compliance with applicable laws and regulations, including those governing cGMPs, they may deny any NDA or marketing application we submit until the deficiencies are corrected or we replace the manufacturer in our application with a manufacturer that is able to demonstrate a compliance status acceptable to the FDA or foreign regulatory authority. Moreover, we are dependent on our CMOs for manufacturing in compliance with cGMPs and other regulatory requirements. In the event that any of our manufacturers fails to comply with such requirements or to perform its obligations in relation to quality, timing or otherwise, or if our projected manufacturing capacity or supply of materials becomes limited, interrupted, or more costly than anticipated, we

may be forced to enter into an agreement with another third party, which we may not be able to do timely or on reasonable terms, if at all. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to the original manufacturer and we may have difficulty transferring such to another third party. These factors would increase our reliance on such manufacturer or require us to obtain a license from such manufacturer in order to enable us, or to have another third party, manufacture our product candidates. We will be required to verify that the new manufacturer maintains facilities and procedures that comply with applicable quality standards and regulations and guidelines; and we may be required to repeat some of the development program. If we are required to change manufacturers, the delays and costs associated with the verification of a new manufacturer, whether due to failure to comply with regulatory requirements, or quality, timing and supply issues, or other reason, could negatively affect our ability to develop product candidates in a timely manner or within budget.

As part of our process development efforts, we also may make changes to the manufacturing processes at various points during development, for various reasons, such as controlling costs, achieving scale, decreasing processing time, improving product formulations, increasing manufacturing success rate or other reasons. For example, we are implementing certain manufacturing process changes for envu to increase scalability with respect to our Phase 3 clinical trials. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our current or future product candidates to perform differently and affect the results of our future clinical trials. In some circumstances, changes in the manufacturing process may require us to perform *ex vivo* comparability studies or clinical bridging studies, and we may be required to collect additional data from participants prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical phases or at earlier portions of a trial to the product used in later clinical phases or later portions of the trial.

We expect to continue to rely on third-party manufacturers if we receive regulatory approval for any product candidate. To the extent that we enter into future long-term manufacturing arrangements with third parties, we will depend on these third parties to perform their obligations in a timely manner consistent with contractual and regulatory requirements, including those related to quality control and assurance. Any manufacturing facilities used to produce our product candidates will be subject to periodic review and inspection by the FDA and comparable foreign regulatory authorities, including for continued compliance with cGMP requirements, quality control, quality assurance and corresponding maintenance of records and documents. If we are unable to obtain or maintain third-party manufacturing for product candidates, or to do so on commercially reasonable terms, we may not be able to develop and commercialize our product candidates successfully. Our or a third party's failure to execute on our manufacturing requirements, comply with cGMPs or maintain a compliance status acceptable to the FDA or comparable foreign regulatory authorities could adversely affect our business in a number of ways, including:

- an inability to initiate or continue preclinical studies or clinical trials of product candidates;
- delay in submitting regulatory applications, or receiving regulatory approvals, for product candidates;
- loss of the cooperation of future collaborators;
- sanctions being imposed on us, including shutdown of the third-party vendor or invalidation of drug product lots or processes, fines, injunctions, civil penalties, delays, suspension, variation or withdrawal of approvals, license revocation, seizures of product candidates or drugs, operating restrictions and criminal prosecutions;
- requirements to cease distribution or to recall batches of our product candidates; and
- in the event of approval to market and commercialize a product candidate, an inability to meet commercial demands for our products.

Additionally, our CMOs may experience difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If our CMOs were to encounter any of these difficulties, our ability to provide our product candidates to participants in preclinical and clinical trials, or to provide product for treatment of participants once approved, would be jeopardized.

We depend on limited source suppliers for certain raw materials used in our product candidates. If we are unable to source these supplies on a timely basis or establish redundancy in our manufacturing process or longer-term contracts with our CMOs, we will not be able to complete our clinical trials on time and the development of our product candidates may be delayed.

Certain of the raw materials necessary to produce envu and A-005 are in limited supply, and we generally rely on one CMO for each manufacturing stage. While we intend to identify and qualify additional suppliers and redundant manufacturers to provide the API, drug product and critical raw material prior to submission of an NDA to the FDA and/or a comparable marketing application outside the United States, there can be no assurance that we will be successful in doing so. Furthermore, any of the limited source suppliers upon whom we rely could stop producing our supplies, cease operations or be acquired by, or enter into exclusive arrangements with, our competitors. Establishing redundancy in CMOs and additional or replacement suppliers for these supplies, and obtaining regulatory authorizations that may result from adding or replacing CMOs and suppliers, could take a substantial amount of time, result in increased costs and impair our ability to produce our products, which would adversely impact our business, financial condition, results of operations and prospects. Any such interruption or delay may force us to seek similar supplies from alternative sources, which may not be available at reasonable prices, or at all. Any interruption in the supply of limited source components for our product candidates would adversely affect our ability to meet scheduled timelines and budget for the development and commercialization of our product candidates, could result in higher expenses and would harm our business. Although we have not experienced any significant disruption as a result of our reliance on limited source suppliers, we have a limited operating history and cannot assure you that we will not experience disruptions in our supply chain in the future as a result of such reliance or otherwise.

In addition, we do not currently have long-term supply contracts with our CMOs, and they are not obligated to supply drug products to us for any period, in any specified quantity or at any certain price beyond the delivery contemplated by the relevant purchase orders. As a result, our suppliers could stop selling to us at commercially reasonable prices, or at all. While we intend to enter into long-term master supply agreements with certain of our CMOs prior to any potential NDA submission, we may not be successful in negotiating such agreements on favorable terms or at all. If we do enter into such long-term master supply agreements, or enter into such agreements on less favorable terms than we currently have with such manufacturers, we could be subject to binding long-term purchase obligations that may be harmful to our business, including in the event that we do not conduct our trials on planned timelines, or at all, or utilize the drug products that we are required to purchase. Any change in our relationships with our CMOs or changes to the contractual terms of our agreements with them could adversely affect our business, financial condition, results of operations and prospects.

The operations of our suppliers, most of which are located outside of the United States, are subject to additional risks that are beyond our control and that could harm our business, financial condition, results of operations and prospects.

Currently, most of our suppliers are located outside of the United States. As a result of our global suppliers, we are subject to risks associated with doing business abroad, including:

- political unrest, terrorism, labor disputes, and economic instability resulting in the disruption of trade from foreign countries in which our products are manufactured;

- the imposition of new laws and regulations, including those relating to labor conditions, quality, and safety standards, imports, duties, taxes, and other charges on imports, as well as trade restrictions and restrictions on currency exchange or the transfer of funds, particularly new or increased tariffs imposed on imports from countries where our suppliers operate;

- fluctuations in currency exchange rates over time, which may substantially increase our costs of doing business abroad where we have payment obligations in local currency;

- greater challenges and increased costs with enforcing and periodically auditing or reviewing our suppliers' and manufacturers' compliance with cGMPs or status acceptable to the FDA or comparable foreign regulatory authorities;

- reduced protection for intellectual property rights, including trademark protection, in some countries particularly China;

- disruptions in operations due to global, regional, or local public health crises or other emergencies or natural disasters, including, for example, disruptions experienced during the COVID-19 pandemic;

- disruptions or delays in shipments; and

- changes in local economic conditions in countries where our manufacturers or suppliers are located.

These and other factors beyond our control could interrupt our suppliers' production, influence the ability of our suppliers to export our clinical supplies cost-effectively or at all, and inhibit our suppliers' ability to procure certain materials, any of which could harm our business, financial condition, results of operations and prospects.

We may be exposed to significant currency exchange risk.

We operate a number of our clinical trials outside of the United States and incur portions of our expenses, and may in the future derive revenues, in a variety of currencies. As a result, we are exposed to currency exchange risk as our results of operations and cash flows are subject to fluctuations in currency exchange rates. Fluctuations in currency exchange rates have had, and will continue to have, an impact on our results as expressed in United States dollars. We currently do not have a formal hedging program with respect to foreign currencies. We cannot predict the impact of foreign currency fluctuations, and foreign currency fluctuations in the future may adversely affect our financial condition, results of operations and cash flows.

Risks Related to Ownership of Our Common Stock

An active and liquid trading market for our common stock may not develop, and you may not be able to resell your shares of common stock at or above the price you paid for them.

An active trading market for our common stock may never develop or, if it is developed, be sustained. The market value of our common stock may decrease from the price you paid for them. As a result of these and other factors, including our limited public float, you may be unable to resell your shares of our common stock at or above the price you paid for them. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies or products by using our shares of common stock as consideration.

Our quarterly and annual operating results may fluctuate significantly or may fall below the expectations of investors or securities analysts or any guidance we may publicly provide, each of which may cause our stock price to fluctuate or decline.

We expect our operating results to be subject to quarterly and annual fluctuations which may, in turn, cause the price of our common stock to fluctuate substantially. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expense related to the ongoing development of our most advanced product candidate envu, A-005 and other development programs;

- results and timing of preclinical studies and ongoing and future clinical trials, or the addition or termination of any such clinical trials;

- the timing of payments we may make or receive under any current or future license and future collaboration

arrangements or the termination or modification thereof;

- our execution of any strategic transactions, including any future acquisitions, collaborations, licenses or similar arrangements, and the timing and amount of payments we may make or receive in connection with such transactions;
- any intellectual property infringement lawsuit or opposition, interference or cancellation proceeding in which we may become involved;
- recruitment and departures of key personnel;
- if our product candidates receive regulatory approval, the terms of such approval and market acceptance and demand for such products;
- regulatory developments affecting our product candidates or those of our competitors;
- fluctuations in stock-based compensation expense;
- the impacts of inflation and rising interest rates on our business and operations; and
- changes in general market and economic conditions.

If our quarterly or annual operating results fall below the expectations of investors or securities analysts or any forecasts or guidance we may provide to the market, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated guidance we may provide. We believe that quarterly or annual comparisons of our financial results are not necessarily meaningful and should not be relied upon as an indication of our future performance.

Our stock price is likely to continue to be volatile, which could result in substantial losses for our investors.

The market price of our common stock is likely to continue to be volatile and could fluctuate widely in response to many factors, including but not limited to:

- announcements regarding our ability and anticipated timelines to submit applications for regulatory approvals of envu in PsO;
- regulatory approval or non-approval of envu in PsO, specific label indications for or restrictions, warnings or limitations in its use or delays in the regulatory review process;
- volatility and instability in the financial and capital markets;
- announcements relating to our product candidates, including the results of clinical trials by us or any future collaborators;
- announcements by competitors that impact our competitive outlook;
- negative developments with respect to our product candidates, or similar products or product candidates with which we compete;
- developments with respect to patents or intellectual property rights;
- announcements of technological innovations, new product candidates, new products or new contracts by us or

our competitors;

- announcements relating to any future strategic transactions, including acquisitions, collaborations, licenses or similar arrangements;
- our ability to achieve the perceived benefits of our strategic transactions, including the ACELYRIN Merger, as rapidly or to the extent anticipated by financial analysts or investors;
- actual or anticipated variations in our operating results due to the level of development expenses and other factors;
- changes in financial estimates by equities research analysts and whether our earnings (or losses) meet or exceed such estimates;
- announcement or expectation of additional financing efforts and receipt, or lack of receipt, of funding in support of conducting our business;
- sales of our common stock by us, our insiders, or other stockholders, or issuances by us of shares of our common stock in connection with strategic transactions;
- conditions and trends in the pharmaceutical, biotechnology and other industries;
- regulatory developments within, and outside of, the United States, including changes in the structure of health care payment systems;
- litigation or arbitration;
- COVID-19 or other pandemics, natural disasters, or major catastrophic events;
- general economic, political and market conditions and other factors; and
- the occurrence of any of the risks described in this section titled "Risk Factors."

In recent years, the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance.

Sales of a substantial number of shares of our common stock could cause our stock price to fall.

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.

We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. However, future sales of substantial amounts of our common stock in the public market or the perception that such sales may occur, could adversely affect the market price of our common stock.

We also expect that significant additional capital may be needed in the future to continue our planned operations, including conducting our planned clinical trials, manufacturing and commercialization efforts, expanded research and development activities and costs associated with operating as a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce

the market price of our common stock.

Our principal stockholders and management own a significant percentage of our common stock and will be able to control matters subject to stockholder approval.

Based on the beneficial ownership of our capital stock as of December 31, 2025, our executive officers, directors, holders of 5% or more of our capital stock and their respective affiliates beneficially owned approximately 41% of our outstanding voting stock. The interests of these stockholders may not be the same as or may even conflict with your interests. For example, these stockholders could delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders, which could deprive our stockholders of an opportunity to receive a premium for their common stock as part of a sale of our company or our assets and might affect the prevailing market price of our common stock. 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. In addition, as a result of this concentration of ownership, there is a limited number of shares of our common stock that are not held by officers, directors and controlling stockholders (which is referred to as our public float), thereby adversely impacting the liquidity of our common stock and potentially depressing the price at which you may be able to sell shares of common stock.

We are an "emerging growth company" and a "smaller reporting company" and the reduced reporting requirements applicable to emerging growth companies and smaller reporting companies may make our common stock less attractive to investors.

We are an "emerging growth company" as defined in Section 2(a) of the Securities Act of 1933, as amended (the "Securities Act"), as modified by the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to the other public companies that are not "emerging growth companies," including (i) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, (ii) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (iii) exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not approved previously. We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting obligations in this report. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. These provisions allow an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have elected to take advantage of such extended transition period. We cannot predict whether investors will find our common stock less attractive as a result of its reliance on these exemptions. If some investors find our common stock to be less attractive as a result, there may be a less active trading market for our common stock and the price of our common stock may be more volatile than the current trading market and price of our common stock.

Further, there is no guarantee that the exemptions available under the JOBS Act will result in significant savings. To the extent that we choose not to use exemptions from various reporting requirements under the JOBS Act, we will incur additional compliance costs, which may impact our financial condition.

We will remain an emerging growth company until the earliest of: (i) the end of the fiscal year in which we have a total annual gross revenue of $1.235 billion; (ii) the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering ("IPO"); (iii) the date on which we have, during the previous three-year period, issued more than $1.0 billion in non-convertible debt; or (iv) the end of the fiscal year in which the market value of common stock held by non-affiliates exceeds $700 million as of the prior June 30. Even after we no longer qualify as an emerging growth company, we may continue to qualify as a smaller reporting company, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation. In addition, as a smaller reporting company with less than $100 million in annual revenue, we are not required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act.

Anti-takeover provisions in our charter documents and under Delaware law could prevent or delay an acquisition of us that may be beneficial to our stockholders and may prevent attempts by our stockholders to replace or remove our current management.

Our amended and restated certificate of incorporation and our amended and restated bylaws contain provisions that could delay or prevent a change in control of our company. These provisions could also make it difficult for stockholders to elect directors who are not nominated by current members of our board of directors or take other corporate actions, including effecting changes in our management. These provisions:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of two-thirds of our stockholders;
- require super-majority voting to amend some provisions in our amended and restated certificate of incorporation and amended and restated bylaws;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan;
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting; and
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings.

In addition, Section 203 of the Delaware General Corporation Law ("DGCL") may discourage, delay or prevent a change in control of our company. Section 203 imposes certain restrictions on mergers, business combinations and other transactions between us and holders of 15% or more of our common stock.

The exclusive forum provisions in our organizational documents may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers or employees, or the underwriters of any offering giving rise to such claim, which may discourage lawsuits with respect to such claims.

Our amended and restated certificate of incorporation, to the fullest extent permitted by law, provides that the Court of Chancery of the State of Delaware is the exclusive forum for: any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising pursuant to the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws; or any action asserting a claim that is governed by the internal affairs doctrine. This exclusive forum provision does not apply to suits brought to enforce a duty or liability created by the Exchange Act.

This choice of forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or any of our directors, officers, or other employees, or the underwriters of any offering giving rise to such claims, which may discourage lawsuits with respect to such claims. Alternatively, if a court were to find the choice of forum provisions contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, financial condition, results of operations and prospects.

Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Our amended and restated bylaws provide that the federal district courts of the United States of America will, to the fullest extent permitted by law,

be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"), including for all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While federal or other state courts may not follow the holding of the Delaware Supreme Court or may determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. In addition, neither the exclusive forum provision nor the Federal Forum Provision applies to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our stockholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must be brought in federal court, and our stockholders cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to our exclusive forum provisions in our amended and restated certificate of incorporation, including the Federal Forum Provision. These provisions may limit a stockholder's ability to bring a claim, and may result in increased costs for a stockholder to bring such a claim, in a judicial forum of their choosing for disputes with us or our directors, officers, other employees or agents, which may discourage lawsuits against us and our directors, officers, other employees or agents.

Our board of directors is authorized to issue and designate shares of our preferred stock without stockholder approval.

Our amended and restated certificate of incorporation authorizes our board of directors, without the approval of our stockholders, to issue shares of preferred stock, subject to limitations prescribed by applicable law, rules and regulations and the provisions of our amended and restated certificate of incorporation, and to establish from time to time the number of shares of preferred stock to be included in each such series and to fix the designation, powers, preferences and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences and rights of these additional series of convertible preferred stock may be senior to or on parity with our common stock, which may reduce our common stock's value.

Because we do not anticipate paying any dividends on our capital stock in the foreseeable future, capital appreciation, if any, will be your sole source of gain.

We have never declared nor paid dividends on our capital stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development, operation and expansion of our business and we do not anticipate declaring or paying any dividends in the foreseeable future. As a result, capital appreciation of our common stock, which may never occur, will be your sole source of gain on your investment for the foreseeable future.

The dual class structure of our common stock may limit your ability to influence corporate matters and may limit your visibility with respect to certain transactions.

The dual class structure of our common stock may limit your ability to influence corporate matters. Holders of our common stock are entitled to one vote per share, while holders of our non-voting common stock are not entitled to any votes. Nonetheless, each share of our non-voting common stock may be converted at any time into one share of our common stock at the option of its holder by providing written notice to us, subject to the ownership and other limitations provided for in our certificate of incorporation. Consequently, if holders of our non-voting common stock exercise their option to make this conversion, this will have the effect of increasing the relative voting power of those prior holders of our non-voting common stock, and correspondingly decreasing the voting power of the holders of our common stock, which may limit your ability to influence corporate matters. Additionally, stockholders who hold, in the aggregate, more than 10% of

our common stock and non-voting common stock, but 10% or less of our common stock, and are not otherwise an insider, may not be required to report changes in their ownership due to transactions in our non-voting common stock pursuant to Section 16(a) of the Exchange Act, and may not be subject to the short-swing profit provisions of Section 16(b) of the Exchange Act.

General Risk Factors

Unstable economic and market conditions may have serious adverse consequences on our business, financial condition and stock price.

Global economic and business activities continue to face widespread uncertainties, and global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability (for example, related to the evolving U.S. and ex-U.S. tariff landscape). The extent of the impact of these conditions on our operational and financial performance, including our ability to execute our business strategies and initiatives in the expected timeframe, as well as that of third parties upon whom we rely, will depend on future developments which are uncertain and cannot be predicted. There can be no assurance that further deterioration in economic or market conditions will not occur, or how long these challenges will persist. If the current equity and credit markets further deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. Furthermore, our stock price may decline due in part to the volatility of the stock market and the general economic downturn.

If securities or industry analysts do not publish research or reports about our business, or if they publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock is influenced in part by the research and reports that industry or securities analysts publish about us or our business. We do not have any control over the industry or securities analysts, or the content and opinions included in their reports and may never obtain research coverage by securities and industry analysts. If no or few securities or industry analysts commence coverage of us, or if analysts cease coverage of us, we could lose visibility in the financial markets, and the trading price for our common stock could be impacted negatively. If any of the analysts who cover us publish inaccurate or unfavorable research or opinions regarding us, our business model, our intellectual property or our stock performance, or if our preclinical studies and clinical trials and operating results fail to meet the expectations of analysts, our stock price would likely decline.

We incur increased costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. The Securities Act, the Exchange Act, Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Select Market and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel will continue to need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, particularly after we are no longer an emerging growth company. We cannot predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. The increased costs may require us to reduce costs in other areas of our business. Moreover, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

Failure to establish and maintain effective internal control over financial reporting could adversely affect our business and if investors lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could be negatively affected.

We are not currently required to comply with the rules of the SEC implementing Section 404(b) of the Sarbanes-Oxley Act which requires including an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. However, we are required to comply with the SEC's rules implementing Sections 302 and 404(a) of the Sarbanes-Oxley Act, which require our management to certify financial and other information in our quarterly and annual reports and provide an annual management report on the effectiveness of internal control over financial reporting. Although we will be required to disclose changes made in our internal control over financial reporting on a quarterly basis, we will not be required to make our first annual assessment of our internal control over financial reporting until our second annual report on Form 10-K. Furthermore, as an emerging growth company, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting until the later of the year following our first annual report required to be filed with the SEC or the date we are no longer an emerging growth company. At such time, our independent registered public accounting firm would need to issue a report that is adverse in the event that there are material weaknesses in our internal control over financial reporting.

To comply with the requirements of being a public company, we have undertaken various actions, and will need to take additional actions, such as implementing numerous internal controls and procedures and hiring additional accounting or internal audit staff or consultants. Testing and maintaining internal controls can divert our management's attention from other matters that are important to the operation of our business. Additionally, when evaluating our internal control over financial reporting, we may identify material weaknesses that we may not be able to remediate in time to meet the applicable deadline imposed upon us for compliance with the requirements of Section 404(b). If we identify any material weaknesses in our internal control over financial reporting or are unable to comply with the requirements of Section 404(b) in a timely manner or assert that our internal control over financial reporting is effective, or if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting once we are no longer an emerging growth company, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be negatively affected, and we could become subject to investigations by the stock exchange on which our securities are listed, the SEC or other comparable foreign regulatory authorities, which could require additional financial and management resources. In addition, if we fail to remedy any material weakness, our financial statements could be inaccurate, and we could face restricted access to capital markets.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

We are subject to the periodic reporting requirements of the Exchange Act. We have designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. Any disclosure controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement causing us to fail to make any related party transaction disclosures. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. In addition, we do not have a formal risk management program for identifying and addressing risks to our business in other areas.

ACELYRIN has been named a defendant in a purported securities class action lawsuit, and we may be the target of other securities litigation in the future. This could result in substantial damages or other expenses and could divert management's time and attention from our business.

In connection with the ACELYRIN Merger, we assumed the liabilities of ACELYRIN, which include a purported federal securities class action lawsuit which was commenced against ACELYRIN in the United States District Court for the

Central District of California (the "Court") on November 15, 2023. On February 15, 2024, the Court appointed joint lead plaintiffs and lead counsel. An amended complaint was filed on March 26, 2024, naming ACELYRIN and current and former officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act in disclosures regarding the primary endpoint of HiSCR75 at week 16 not meeting statistical significance in ACELYRIN's Phase 2b trial of izokibep in hidradenitis suppurativa. The amended complaint seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the court may deem just and proper. On May 3, 2024, the defendants filed their motion to dismiss the amended complaint, which was granted by the court, with leave to amend, in January 2026. On February 5, 2026, the plaintiffs filed a second amended complaint which seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the court may deem just and proper. On February 19, 2026, the defendants filed their motion to dismiss the second amended complaint, which remains pending. This lawsuit is subject to inherent uncertainties, including its outcome. We could be forced to expend significant resources and incur substantial legal fees and costs in the defense of this suit, and we may not prevail. We have not established any reserve for any potential liability relating to this lawsuit. It is possible that we could, in the future, incur judgments or enter into settlements of claims for monetary damages. In addition, we may be the target of other securities litigation in the future. Securities litigation (including the cost to defend against, and any potential adverse outcome resulting from any such proceeding) can be expensive and time-consuming, damage our reputation and divert our management's attention from other business concerns, which could seriously harm our business.

Item 1B. Unresolved Staff Comments

None.

Item 1C. Cybersecurity

Risk Management and Strategy

We manage cybersecurity risks utilizing a risk-based approach that incorporates various information security processes designed to identify, assess and manage risks from cybersecurity threats, including potential unauthorized access to our critical information technology systems and data. Depending on the environment, we maintain certain controls, systems, and other processes designed to identify, assess and manage our cybersecurity threats and risks, such as: maintaining network security controls, maintaining email security tools, utilizing certain third-party managed security services, such as managed detection and response, monitoring threat intelligence bulletins, conducting penetration tests and vulnerability scans, maintaining cybersecurity insurance, and conducting periodic employee cybersecurity training.

Our assessment and management of material risks from cybersecurity threats are integrated into the Company's overall enterprise risk management processes. For example, we evaluate and manage material risks arising from cybersecurity threats, along with other significant risks we face, against our overall business objectives and within our overall enterprise risk management practices. The audit committee of our board of directors (the "Audit Committee") evaluates our overall enterprise risks.

We use service providers to assist us from time to time in our efforts to identify, assess, and manage material risks from cybersecurity threats, including for example, outside security consultants and vendors, third party penetration testing providers, and forensic providers.

Further, we use third-party service providers to perform a variety of functions throughout our business, such as software-as-a-service providers, data hosting companies, and CROs. We maintain a vendor risk management process designed to help manage cybersecurity risks associated with our use of these providers. Depending on the nature of the services provided, the sensitivity of the Company systems and data at issue, and the identity of the provider, our vendor risk management process may involve different levels of assessment designed to help identify cybersecurity risks associated with a provider, including, for example, security questionnaires and the imposition of contractual obligations related to cybersecurity on the provider.

For a description about risks from cybersecurity threats that may materially affect the Company and how they may do so, see our Risk Factors under Part I, Item 1A., under the heading *"If our information technology systems, or those used by*

our CROs, CMOs, clinical sites or other third parties with whom we work, or our data are or were compromised, become unavailable or suffer security breaches, loss or leakage of data or other disruptions, we could suffer material adverse consequences resulting from such compromise, including but not limited to, operational or service interruption, harm to our reputation, regulatory investigations or actions, litigation, fines, penalties and liability, and other adverse consequences to our business, results of operations, and financial condition."

Governance

The board of directors addresses the Company's cybersecurity risk management as part of its general oversight function. The Audit Committee has been designated by our board of directors to oversee the Company's cybersecurity risk management process, including oversight of mitigation of risks from cybersecurity threats.

Our cybersecurity risk assessment and management processes are implemented and maintained by a dedicated information technology team, led by our Executive Director of Information Technology who has over twenty years of experience managing information technology systems and cybersecurity risks and who reports directly to our Chief Financial Officer. Our Executive Director of Information Technology is responsible for hiring appropriate personnel, helping to integrate cybersecurity risk considerations into the Company's overall risk management strategy, and communicating key priorities to relevant personnel. Our Executive Director of Information Technology, together with certain other senior management personnel, is responsible for approving functional cybersecurity budgets, implementing approved, phase-appropriate cybersecurity policies, plans and/or guidelines, reviewing security assessments and other security-related reports and overseeing cybersecurity processes.

Our incident response processes are designed to escalate certain incidents to members of management (including the Chief Financial Officer) depending on the circumstances. Our Executive Director of Information Technology works with the Company's cybersecurity incident responders to help the Company mitigate and remediate cybersecurity incidents of which they are notified. The Company's incident response processes also include reporting to the Disclosure Committee and the Audit Committee for certain cybersecurity incidents. In addition, the Audit Committee receives periodic updates on cybersecurity risks and information technology matters, including related risk exposures and the processes the Company has implemented which are designed to address them, from management.

Item 2. Properties

Our principal executive offices are located in South San Francisco, California. We entered into the lease for our principal executive offices in August 2022, for approximately 55,000 square feet of combined office and laboratory space in South San Franscisco, which will expire in August 2033. In December 2024, we entered into a lease for approximately 22,000 square feet of additional office space in South San Francisco, California which will end in December 2026.

Upon the closing of the ACELYRIN Merger, the Company became the successor to ACELYRIN's rights under ACELYRIN's lease agreements that included approximately 10,012 square feet of office space in Southern California, which expires in August 2028, and approximately 22,365 square feet of office space in South San Francisco, California, which expires in October 2029. Both facilities have been subleased through the end of their lease terms.

We believe our facilities are adequate and suitable for our current needs, and that should it be needed, suitable additional or alternative space will be available to accommodate our operations.

Item 3. Legal Proceedings

On November 15, 2023, a purported federal securities class action lawsuit was commenced in the United States District Court for the Central District of California. On February 15, 2024, the Court appointed joint lead plaintiffs and lead counsel. An amended complaint was filed on March 26, 2024 (Boukadoum v. Acelyrin, Inc. et al., No. 2:23-cv-09672-F MO-MAA), naming ACELYRIN and then-current and former executive officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act by misleading investors about the Phase 2b trial of izokibep in hidradenitis suppurativa. The original complaint was filed following ACELYRIN's announcement of the week 16 results from the Part B portion of such Phase 2b trial. The amended complaint seeks damages

and an award of reasonable costs and expenses, including attorneys' fees, expert fees and other costs, as well as such other and further relief as the court may deem just and proper. On May 3, 2024, the defendants filed their motion to dismiss the amended complaint, which was granted by the court, with leave to amend, in January 2026. On February 5 2026, the plaintiffs filed a second amended complaint, which seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the court may deem just and proper. On February 19, 2026, the defendants filed their motion to dismiss the second amended complaint, which remains pending. It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming us and or our officers and directors as defendants. This lawsuit and any other potential lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. We could be forced to expend significant resources in the defense against this and any other related lawsuits and we may not prevail.

From time to time, we may become involved in additional legal proceedings arising in the ordinary course of business. Regardless of outcome, such proceedings or claims can have an adverse impact on us because of defense and settlement costs, diversion of resources, negative publicity, reputational harm and other factors, and there can be no assurances that favorable outcomes will be obtained.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Common Stock

Our voting common stock has been listed on The Nasdaq Global Select Market under the symbol "ALMS" since June 28, 2024. Prior to that date, there was no public market for our common stock.

Holders of Common Stock

As of March 12, 2026, there were 47 stockholders of record of our voting common stock and 2 stockholders of our non-voting common stock. Because many of our voting common stock are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividend Policy

We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock. We intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business. Any future determination regarding the declaration and payment of dividends, if any, will be at the discretion of our board of directors, subject to applicable laws, and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, and other factors our board of directors may deem relevant. In addition, our ability to pay cash dividends on our capital stock in the future may be limited by the terms of any future debt or preferred securities we issue or any credit facilities we enter into.

Unregistered Sales of Equity Securities

Since January 1, 2025, we have not issued any unregistered securities.

Purchases of Equity Securities by Issuers and Affiliated Purchasers

None.

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 our consolidated financial statements and the related notes and other financial information included elsewhere in this Annual Report on Form 10-K. This discussion and analysis and other parts of this Annual Report on Form 10-K contain forward-looking statements based upon current beliefs, plans and expectations related to future events and our future financial performance that involve risks, uncertainties and assumptions, such as statements regarding our intentions, plans, objectives and expectations for our business. Our actual results and the timing of selected events could differ materially from those described in or implied by these forward-looking statements as a result of several factors, including those set forth under Part I, Item 1A. "Risk Factors" in this Annual Report on Form 10-K. See also the section titled "Special Note Regarding Forward-Looking Statements."

Overview

Our mission is to significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies. Our name, Alumis, captures our mission to enlighten immunology, and is inspired by the words "allumer"—French for illuminate—and "immunis"—Latin for the immune system.

We are a clinical stage biopharmaceutical company with an initial focus on developing our two TYK2 inhibitors: envu, formerly known as ESK-001, a second-generation inhibitor that we are developing to maximize target inhibition and optimize tolerability, and A-005, a CNS penetrant molecule. Envu is currently being evaluated in an ongoing Phase 2 OLE trial, as well as a Phase 3 LTE trial in patients with PsO and we plan to submit an NDA for envu in PsO to the FDA in the second half of 2026. Envu completed enrollment in the pivotal Phase 3 ONWARD1 and ONWARD2 clinical trials in patients with PsO, and we reported positive topline results in the first quarter of 2026. In addition, envu is currently being evaluated in a Phase 2 clinical trial in patients with SLE, for which we expect to report topline results in the third quarter of 2026. We are currently evaluating additional immune-mediated disease indications for envu, beyond PsO and SLE, and for A-005 in CNS and peripheral diseases. In April 2024, we initiated our Phase 1 program of A-005 in healthy volunteers and reported initial results in December 2024. In addition, in connection with the ACELYRIN Merger, we acquired lonigutamab, a subcutaneously delivered, monoclonal antibody targeting IGF-1R for the potential treatment of TED. We are continuing to evaluate the development program for lonigutamab and its potential differentiation in a capital efficient manner.

Alumis was incubated by Foresite Labs and incorporated on January 29, 2021, as a Delaware corporation under the name FL2021-001, Inc. FL2021-001, Inc.'s name was changed to Esker Therapeutics, Inc. in March 2021, and to Alumis Inc. in January 2022.

Since our inception, we have devoted substantially all of our efforts to organizing our company, hiring personnel, business planning, acquiring and developing our product candidates, performing research and development, conducting preclinical studies and clinical trials, establishing and protecting our intellectual property portfolio, raising capital, integrating the acquired ACELYRIN business and personnel, and providing general and administrative support for these activities. We do not have any products approved for sale and have not generated any revenue from product sales. We expect to continue to incur significant and increasing expenses and increasing substantial losses for the foreseeable future as we continue our development of and seek regulatory approvals for our product candidates and commercialize any approved products, seek to expand our product pipeline and invest in our expanded organization following the ACELYRIN Merger. Our ability to achieve and sustain profitability will depend on our ability to successfully develop, obtain regulatory approval for and commercialize our product candidates. There can be no assurance that we will ever achieve profitability, or if achieved, that the revenue or profitability will be sustained on a continuing basis.

To date, we have primarily funded our operations primarily through issuance of common stock, including in connection with the ACELYRIN Merger, our IPO and private placement transaction, the issuance of redeemable convertible preferred stock and convertible promissory notes in private placements, payments received under the Kaken Collaboration Agreement and, most recently, the public offering of common stock which closed on January 9, 2026. In addition, on March 18, 2026, we entered into a Sales Agreement with Cantor, pursuant to which we may offer and sell, from time to time through Cantor, at our option, shares of our common stock having an aggregate offering price of up to $300.0 million.

As of December 31, 2025, we had $308.5 million in cash, cash equivalents and marketable securities.

We have incurred significant operating losses and negative cash flows since our inception. Our net loss for the years ended December 31, 2025 and 2024 was $243.3 million and $294.2 million, respectively. As of December 31, 2025, we had an accumulated deficit of $901.9 million. Substantially all of our net losses have resulted from costs incurred in connection with our research and development efforts, including acquisitions of in-process research and development assets, and, to a lesser extent, from general and administrative costs associated with our operations. Our net losses and operating losses may fluctuate from quarter to quarter and year to year depending primarily on the timing of acquisition of any new product candidates, the timing of our preclinical studies and clinical trials, our other research and development expenses, and the timing and amount of any milestone or royalty payments due under our existing or future license agreements. We have incurred and will continue to incur costs associated with operating as a public company, including significant legal, audit, accounting, regulatory and tax-related services associated with maintaining compliance with exchange listing and SEC requirements, director and officer liability insurance costs, investor and public relations costs, and other expenses.

We anticipate that our expenses will increase significantly in connection with our ongoing activities, particularly if and as we:

- continue to progress the development of our product candidates in multiple clinical trials in parallel;
- prepare to submit an NDA for envu in PsO in the second half of 2026, including as we conduct activities, including CMC activities, that are required to complete our planned NDA submission;
- explore additional indications for our existing product candidates;
- hire additional clinical and scientific personnel;
- obtain, maintain, expand and protect our intellectual property rights;
- make royalty, milestone or other payments under our stock purchase agreement of FronThera U.S. Holdings, Inc. and its wholly owned subsidiary, FronThera U.S. Pharmaceuticals LLC, in March 2021 (the "FronThera Acquisition"), the March 25, 2021 license and commercialization agreement with Pierre Fabre, as amended (the "Pierre Fabre Agreement"), the Kaken Collaboration Agreement and any future license or collaboration agreements;
- seek to identify, acquire or in-license new technologies or product candidates;
- seek regulatory and marketing approvals for any of our product candidates that successfully complete clinical trials, if any;
- procure manufacturing and supply chain capacity for our product candidates, including commercial manufacturing readiness and scale-up;
- experience any delays, challenges or other issues associated with the clinical development and regulatory approvals of our product candidates;
- add operational, legal, financial and management information systems and personnel to support our product development, clinical execution and planned future commercialization efforts, as well as to support our operating as a public company;
- establish a sales, marketing and distribution infrastructure to commercialize any product candidates for which we obtain marketing approval; and
- operate as a public company.

We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and 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 collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

We do not currently own or operate any manufacturing facility. We rely on CMOs to produce our product candidates in accordance with the FDA current cGMP regulations for use in our clinical studies. We have entered into development and manufacturing agreements with various CMOs relating to process development, manufacturing of drug substance and drug product, and quality testing of our product candidates. We expect to rely on our CMOs in the future for the manufacturing of our product candidates in order to expedite readiness for future clinical trials. Most of these CMOs have demonstrated capability in preparation of materials for commercialization. Additionally, we may decide to build our own manufacturing facility in the future to provide us with greater flexibility and control over our clinical or commercial manufacturing needs.

Given our stage of development, we do not yet have a fully established marketing or sales organization or commercial infrastructure; however, we have begun building foundational capabilities and intend to continue expanding the necessary sales, marketing and commercialization capabilities and infrastructure over time as our product candidates advance through clinical development and regulatory approval. We expect to spend a significant amount in commercial development and marketing costs prior to obtaining regulatory and marketing approval of one or more of our product candidates.

IPO and Concurrent Private Placement

On July 1, 2024, we completed our IPO, pursuant to which we issued and sold 13,125,000 shares of our common stock at $16.00 price per share to the public. Net proceeds from the IPO were $193.3 million, after deducting underwriting discounts and commissions and other offering costs totaling $16.7 million. In connection with the IPO, on July 17, 2024, an existing investor and a holder of more than 5% of our capital stock, purchased an additional 2,500,000 shares of our common stock at the IPO price per share for total gross and net proceeds of $40.0 million in a private placement transaction (the "Concurrent Private Placement").

Immediately prior to the closing of the IPO on July 1, 2024, all of the shares of our redeemable convertible preferred stock then outstanding converted into 28,855,656 shares of Class A common stock and 7,184,908 shares of Class B common stock at a 1-for-4.675 conversion ratio. All outstanding Class A common stock shares and all outstanding Class B common stock shares were redesignated immediately thereafter into the same number of shares of common stock and non-voting common stock, respectively.

ACELYRIN Merger

On February 6, 2025, we entered into a Merger Agreement with ACELYRIN and Merger Sub, a Delaware corporation and a direct wholly owned subsidiary. The Merger Agreement was approved by the disinterested directors on our board of directors and the board of directors of ACELYRIN and was approved by the stockholders of each company on May 13, 2025. On May 21, 2025, we completed the ACELYRIN Merger for a purchase consideration of approximately $238.1

million that included the issuance of 48,653,549 shares of our common stock and the fair value of replacement awards attributable to pre-combination services, to acquire net assets with a fair value of approximately $426.0 million. See Note 3 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Our results of operations include the accounts of our wholly owned subsidiaries ACELYRIN and WH2, LLC after the closing of the ACELYRIN Merger, and the accounts of Merger Sub from its incorporation in January 2025 until the ACELYRIN Merger. Accordingly, the results discussed below were impacted by the timing of the ACELYRIN Merger. WH2, LLC has not had any operations or any balances since the closing of the ACELYRIN Merger.

Public Offering of Common Stock

On January 7, 2026, we entered into an underwriting agreement (the "Underwriting Agreement") with Morgan Stanley & Co. LLC, Leerink Partners LLC and Cantor, as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to the issuance and sale in a public offering of 17,650,000 shares of our common stock at a price of $17.00 per share. In addition, we granted the Underwriters an option, exercisable for 30 days, to purchase up to 2,647,500 additional shares of common stock at the public offering price, less the underwriting discounts and commissions, which was exercised in full on January 8, 2026. On January 9, 2026, the offering closed and we received net proceeds of $324.4 million, after deducting underwriting discounts and commissions.

Macroeconomic Trends

Our business and results of operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges and uncertainty in the markets, including severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability (for example, related to the evolving U.S. and ex-U.S. tariff landscape). Further, the United States and other countries have imposed and may continue to impose new trade restrictions and export regulations, have levied tariffs and taxes on certain goods, and could continue to significantly increase tariffs on a broad array of goods. For example, in April 2025, the U.S. government imposed a 10% baseline global tariff and in August 2025, the United States imposed higher "reciprocal" tariffs on numerous other territories, including EU member states and South Korea. While the U.S. Supreme Court recently issued a ruling invalidating tariffs imposed by the Trump administration under the International Emergency Economic Powers Act, other tariffs imposed by the U.S. government remain in place, including the 10% global tariff imposed by the Trump administration under Section 122 of the Trade Act of 1974 following the U.S. Supreme Court decision. Moreover, the Bureau of Industry and Security, U.S. Department of Commerce, has initiated an investigation to determine whether pharmaceutical ingredients, including finished drug product, manufactured outside the United States pose a national security risk and should be subject to additional tariffs. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. Moreover, negative macroeconomic conditions could adversely impact our ability to obtain financing in the future on terms acceptable to us, or at all. To date, the macroeconomic trends discussed above have not had a material adverse impact on our business, financial condition or results of operations. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed.

Components of Results of Operations

Revenue

On March 25, 2025, we entered into the Kaken Collaboration Agreement. Under the terms of the Kaken Collaboration Agreement, we granted to Kaken an exclusive right to develop, manufacture and commercialize envu for dermatology indications in Japan, with options to expand the license, subject to opt-in payments and certain cost-sharing obligations on the part of Kaken, to include rheumatological and gastrointestinal diseases.

Pursuant to the terms of the Kaken Collaboration Agreement, we are responsible for the global development of envu in the dermatology field, and Kaken is responsible for the clinical development, regulatory approvals and commercialization

of envu in Japan in dermatology and other indications for which Kaken has exercised its option. Kaken is required to use commercially reasonable efforts to conduct all subsequent development, manufacture, and commercialization activities. The Kaken Collaboration Agreement further provides that we will retain rights to envu in all other indications and geographies.

In March 2025, Kaken made an upfront, non-refundable payment of $20.0 million to us. In addition, Kaken will pay us an aggregate of $20.0 million towards global development costs of envu in the dermatology field through the end of 2026 and thereafter will pay a specified share of development costs applicable to the dermatology field, and for any field for which Kaken exercises its option, subject to Kaken's right to opt out of cost-sharing in certain indications in specified circumstances. In addition, Kaken would pay us up to an aggregate of $36.0 million upon the achievement of regulatory milestones and upon Kaken's exercise of its field expansion options for the rheumatology and gastrointestinal fields. In addition, we are entitled to receive aggregate payments of up to ¥15.5 billion upon the achievement of commercial milestones, plus tiered royalties at percentages ranging from the low double digits into the twenties on aggregate net sales of envu in Japan.

Operating Expenses

Our operating expenses consist of (i) research and development expenses and (ii) general and administrative expenses, and include ACELYRIN's operations subsequent to the Closing Date.

Research and Development Expenses

Research and development expenses consist of external and internal costs primarily related to acquiring and developing our research pipeline and technologies and clinical development of our product candidates.

External costs include:

- costs associated with acquiring technology and intellectual property licenses that have no alternative future uses and costs incurred under in-license or assignment agreements, including milestone payments;
- expenses incurred in connection with the discovery and preclinical development of our pipeline programs;
- costs incurred in connection with the clinical development of our product candidates, including under agreements with CROs, CMOs and other third parties that conduct clinical trials and manufacture clinical supplies, product candidates and components on our behalf; and
- costs for third-party professional research and development consulting services.

Internal costs include:

- research and development personnel-related costs, including salaries, annual bonuses, benefits, travel and meals expenses and stock-based compensation expense; and
- allocated facilities and other overhead costs, including software licenses, computer supplies and accessories and other miscellaneous expenses.

We have acquired and may continue to acquire the rights to develop and commercialize new product candidates. Upfront payments related to acquired IPR&D assets are recognized as expenses when we determine that the assets acquired do not have alternative future uses. Milestone payments are accrued and expensed when the achievement of the milestone is probable up to the point of regulatory approval and, absent obtaining such approval, have no alternative future use. Milestone payments made after a product's regulatory approval will be capitalized and amortized over the remaining useful life of the related product.

We expense research and development costs as incurred. Costs of certain activities are recognized based on an evaluation of the progress to completion of specific tasks. However, payments made prior to the receipt of goods or services that will be used or rendered for future research and development activities are deferred and capitalized as research and development prepaid expenses in our consolidated balance sheets. The capitalized amounts are recognized as expense as the goods are delivered or services are performed. Since our inception and through December 31, 2025, our external research and development expenses were primarily related to the discovery and advancement of programs under our TYK2 platform, including our two most advanced product candidates, envu and A-005. We use internal resources primarily for managing our research, process development, manufacturing and clinical development activities. In particular, with respect to internal costs, we deploy our personnel across all of our research and development activities as our employees work across multiple programs, and therefore the costs cannot be allocated to a particular product candidate or research program.

We expect our research and development expenses to increase substantially for the foreseeable future as we advance our product candidates into and through clinical trials, pursue regulatory approval of our product candidates, build our operational and commercial capabilities for marketing our products, if approved, and expand our pipeline of product candidates. The process of conducting the necessary clinical research to obtain regulatory approval is time-consuming, expensive and uncertain. The actual probability of success for our product candidates may be affected by a variety of factors, including the safety and efficacy of our product candidates, clinical data, investment in our clinical programs, competition, manufacturability and commercial viability. It is possible that we may never receive regulatory approval for any of our product candidates. As a result of the uncertainties discussed above, we are unable to determine the duration and completion of costs of our research and development projects or if, when and to what extent we will generate revenue from the commercialization and sale of our product candidates, if approved by the FDA and other comparable foreign regulatory authorities.

Our future research and development costs may vary significantly based on factors such as:

- the timing and progress of our preclinical and clinical development activities;
- the number and scope of preclinical and clinical programs we decide to pursue;
- the costs and timing of manufacturing of our product candidates;
- the amount and timing of any milestone payment due under our FronThera Acquisition, Pierre Fabre Agreement, the Kaken Collaboration Agreement and any future license or collaboration agreements;
- the number of patients that participate in our clinical trials, and per participant clinical trial costs;
- the number and duration of clinical trials required for approval of our product candidates;
- the number of sites included in our clinical trials, and the locations of those sites;
- delays or difficulties in adding trial sites and enrolling participants;
- patient drop-out or discontinuation rates;
- additional safety monitoring if requested by regulatory authorities;
- the phase of development of our product candidates;
- the timing, receipt and terms of any approvals from applicable regulatory authorities including the FDA and comparable foreign regulatory authorities;
- maintaining a continued acceptable safety profile of our product candidates following approval, if any, of our product candidates;

- changes in the competitive outlook;
- the extent to which we establish additional strategic collaborations or other arrangements; and
- the impact of any business interruptions to our operations or to those of the third parties with whom we work.

A change in the outcome of any of these variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate.

General and Administrative Expenses

Our general and administrative expenses consist primarily of personnel-related costs, legal and consulting services, including those relating to intellectual property and corporate matters, marketing expenses and allocated facilities and other overhead costs, including software licenses, computer supplies, insurance and other miscellaneous expenses. Personnel-related costs include salaries, annual bonuses, benefits, travel and meal expenses and stock-based compensation expense for our general and administrative personnel.

We expect that our general and administrative expenses will increase substantially in the future as a result of expanding our operations, including hiring personnel, preparing for potential commercialization of our product candidates and facility occupancy costs. We also expect to continue incurring costs associated with being a public company, including costs related to accounting, audit, legal, consulting fees, regulatory and tax-related services associated with maintaining compliance with applicable Nasdaq and SEC requirements, additional director and officer insurance costs, and investor and public relations costs.

Other Income (Expense)

Other income (expense) consists primarily of interest income, including amortization of premiums and accretion of discounts on marketable securities, gain on bargain purchase and change in fair value of derivative liability.

At the closing of the ACELYRIN Merger in May 2025, we recognized a gain on bargain purchase which represents the excess of fair value of net assets acquired in the ACELYRIN Merger over the purchase consideration on the Closing Date. The gain on bargain purchase was recognized as other income in the consolidated statements of operations and comprehensive loss as of the Closing Date of the ACELYRIN Merger. See Note 3 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

In March 2024, in connection with our redeemable convertible preferred stock financings, we issued options to purchase additional shares of redeemable convertible preferred stock at a specified price, which were accounted for as derivative liabilities. Changes in fair value of these derivative liabilities were included in the other income (loss) in the consolidated statement of operations and comprehensive loss for each reporting period until the derivatives were settled in May 2024.

Results of Operations and Comprehensive Loss

Comparison of the Years Ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024 (dollars in thousands):

	Year Ended December 31,		Change	
	2025	2024	$	%
Revenue:				
License revenue	$ 17,389	$ —	$ 17,389	*
Collaboration revenue	6,661	—	6,661	*
Total revenue	24,050	—	24,050	*
Operating expenses:				
Research and development expenses	385,998	265,554	120,444	45 %
General and administrative expenses	91,856	35,200	56,656	161 %
Total operating expenses	477,854	300,754	177,100	59 %
Loss from operations	(453,804)	(300,754)	(153,050)	51 %
Other income (expense):				
Gain on bargain purchase	187,907	—	187,907	*
Interest income	14,180	12,020	2,160	18 %
Change in fair value of derivative liability	—	(5,406)	5,406	(100)%
Other income (expense), net	(169)	(93)	(76)	82 %
Total other income (expense), net	201,918	6,521	195,397	*
Net loss before income taxes	(251,886)	(294,233)	42,347	(14)%
Income tax benefit	8,561	—	8,561	*
Net loss	$ (243,325)	$ (294,233)	$ 50,908	(17)%

* not meaningful

Revenue

For the year ended December 31, 2025, we recognized license revenue of $17.4 million and collaboration revenue of $6.7 million, related to the Kaken Collaboration Agreement. At inception of the contract, we allocated the transaction price to the License Obligation and Development Services Obligation by allocating the transaction price based on the relative standalone selling price of each obligation. The license revenue was recognized upon the transfer of the license to Kaken in March 2025. We expect to recognize revenue under the Development Services Obligation and Manufacturing Services Obligation through the term of the Kaken Collaboration Agreement as the services are performed. See Note 7 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Research and Development Expenses

The following table summarizes our external and internal research and development expenses for the years ended December 31, 2025 and 2024 (dollars in thousands):

	Year Ended December 31,		Change	
	2025	2024	$	%
External costs:				
Milestones related to previously acquired IPR&D assets	$ —	$ 23,000	$ (23,000)	(100)%
CROs, CMOs and clinical trials	231,118	151,422	79,696	53 %
Professional consulting services	30,157	19,154	11,003	57 %
Other research and development costs	9,096	10,258	(1,162)	(11)%
Internal costs:				
Personnel-related costs	92,702	46,774	45,928	98 %
Facilities and overhead costs	22,925	14,946	7,979	53 %
Total research and development expense	$ 385,998	$ 265,554	$ 120,444	45 %

* not meaningful

Research and development expenses increased by $120.4 million, to $386.0 million for the year ended December 31, 2025, from $265.6 million for year ended December 31, 2024.

Milestones related to previously acquired IPR&D assets for the year ended December 31, 2024, included a $23.0 million clinical milestone payment made in connection with the FronThera Acquisition.

CRO, CMO and clinical trials expenses increased by $79.7 million, to $231.1 million for the year ended December 31, 2025, from $151.4 million for the year ended December 31, 2024, primarily due to an increase in clinical trial and CRO expenses related to the progression of our clinical trials for envu and other programs, including costs to support acceleration of clinical trial activities for our Phase 3 ONWARD clinical program, partially offset by a decrease in CMO expenses associated with manufacturing of clinical supplies to support our trials.

Professional consulting services expenses increased by $11.0 million, to $30.2 million for the year ended December 31, 2025, from $19.2 million for the year ended December 31, 2024, primarily due to services to support our clinical trial for envu and other programs.

Other research and development costs decreased by $1.2 million, to $9.1 million for the year ended December 31, 2025, from $10.3 million for the year ended December 31, 2024, primarily due to the timing of preclinical studies.

Personnel-related costs increased by $45.9 million, to $92.7 million for the year ended December 31, 2025, from $46.8 million for the year ended December 31, 2024, primarily due to an increase in research and development headcount and severance costs related to the ACELYRIN Merger, and included an increase in stock-based compensation expense of $11.2 million resulting from equity awards assumed in the ACELYRIN Merger and additional stock options granted.

Facilities and overhead costs increased by $8.0 million, to $22.9 million for the year ended December 31, 2025, from $14.9 million for the year ended December 31, 2024, primarily due to an increase in facility expenses allocated to research and development activities and an increase in information technology costs.

External Costs by Program

The following table summarizes our external costs by program for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Envu	$ 224,006	$ 149,941
Lonigutamab	11,905	—
A-005	10,293	19,035
Other programs and research and development activities	24,167	34,858
Total external research and development expense	$ 270,371	$ 203,834

During the years ended December 31, 2025 and 2024, our external research and development expenses were primarily related to the clinical development of our envu program and, to a lesser extent, the lonigutamab and A-005 development programs and our research pipeline.

General and Administrative Expenses

General and administrative expenses increased by $56.7 million, to $91.9 million for the year ended December 31, 2025, from $35.2 million for the year ended December 31, 2024.

Personnel-related expenses increased by $28.8 million, to $48.9 million for the year ended December 31, 2025, from $20.0 million for the year ended December 31, 2024, primarily due an increase in general and administrative headcount and severance costs related to the ACELYRIN Merger, and included an increase in stock-based compensation expense of $12.9 million resulting from equity awards assumed in the ACELYRIN Merger and additional stock options granted.

Professional consulting services expenses increased by $28.1 million, to $41.4 million for the year ended December 31, 2025, from $13.3 million for the year ended December 31, 2024, primarily due to the ACELYRIN Merger transaction costs, a loss reserve and an increase in consulting, audit and tax, legal and accounting services to support our growth, public company requirements and business development.

Other Income (Expense), Net

Other income (expense), net increased by $195.4 million, to $201.9 million for the year ended December 31, 2025, from $6.5 million for the year ended December 31, 2024.

A gain on bargain purchase of $187.9 million was recognized at the Closing Date of the ACELYRIN Merger. No such gain was recognized in any other reporting period.

Interest income increased by $2.2 million, to $14.2 million for the year ended December 31, 2025, from $12.0 million for the year ended December 31, 2024, primarily as a result of higher balances of cash equivalents and marketable securities.

We recognized a change in fair value of a derivative liability loss of $5.4 million for the year ended December 31, 2024 related to the derivative liability recognized in connection with our Series C redeemable convertible preferred stock financing entered into in March 2024. The derivative liability was re-measured at fair value and settled in May 2024, when we closed the second tranche of the Series C financing.

Income Tax Benefit

Income tax benefit was $8.6 million for the year ended December 31, 2025, as compared to zero for the year ended December 31, 2024. The income tax benefit was related to the realization of deferred tax assets and valuation allowance release as a result of the ACELYRIN Merger.

Liquidity, Capital Resources and Capital Requirements

Sources of Liquidity

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses and negative cash flows from our operations. To date, we have primarily funded our operations through the issuance of common stock, including in connection with the ACELYRIN Merger, our IPO and Concurrent Private Placement, the issuance of redeemable convertible preferred stock and convertible promissory notes in private placements and, most recently, our public offering of common stock which closed on January 9, 2026.

On March 18, 2026, we entered into the Sales Agreement with Cantor as sales agent, pursuant to which we may offer and sell, from time to time through Cantor, at our option, shares of our common stock having an aggregate offering price of up to $300.0 million (the "ATM Shares"). The sales of the ATM Shares will be made by any method permitted that is deemed to be an "at-the-market" equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq Global Select Market. We agreed to pay Cantor a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold by Cantor.

Based on our current operating plan, our existing cash, cash equivalents and marketable securities of $308.5 million as of December 31, 2025, as well as net proceeds of $324.4 million, after deducting underwriting discounts and commissions, from our public offering of common stock, which closed on January 9, 2026, will be sufficient to meet our operating and capital requirements for at least 12 months from the date of issuance of our consolidated financial statements included in Part II. Item 8 of this Annual Report on Form 10-K. We expect to continue to incur substantial losses for the foreseeable future, and our transition to profitability will depend upon successful development, approval and commercialization of our product candidates and upon achievement of sufficient revenues to support our cost structure. We do not expect to generate any revenue from commercial product sales unless and until we successfully complete development and obtain regulatory approval for one or more of our product candidates. We may never achieve profitability, and unless we do and until then, we will need to continue to raise additional capital. We will need to raise significant additional capital to fund ongoing research and development activities and maintain future operations. We continuously monitor and, where necessary, may reduce our operating expenses in response to our clinical development progress and our ability and need to raise additional capital through a combination of public and private equity, debt financings, strategic alliances, and licensing arrangements. For example, should any of our ongoing trials not meet our clinical development objectives, we may scale back or discontinue related activities and reallocate our working capital to extend our ability to meet our operating and capital requirements. Our ability to access capital when needed is not assured and, if capital is not available to us when, and in the amounts, needed, on the terms which are favorable, we could be required to delay, scale back, or abandon some or all of our planned development programs and other operations, which could materially harm our business, financial condition and results of operations.

Future Funding Requirements

Our primary uses of cash are to fund our operations, which consist primarily of research and development expenditures related to our programs and, to a lesser extent, general and administrative expenditures. We anticipate that we will continue to incur significant and increasing expenses for the foreseeable future as we continue to advance our product candidates, expand our corporate infrastructure, including the costs associated with being a public company, further our research and development initiatives for our product candidates, and incur costs associated with potential commercialization. We are subject to all of the risks typically related to the development of new drug candidates, and we may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. We anticipate that we will need substantial additional funding in connection with our continuing operations.

We do not have any products approved for sale and have not generated any revenue from product sales since our inception. We do not expect to generate revenue from any product candidates that we develop until we obtain regulatory approval for one or more of such product candidates and commercialize our products or enter into collaboration agreements with third parties. Because of the numerous risks and uncertainties associated with biopharmaceutical product development, we may never achieve or sustain profitability and, unless and until we are able to develop and commercialize our product candidates, we will need to continue to raise additional capital. Until such time as we can generate significant revenue

from product sales, if ever, we expect to finance our operations through public or private equity or debt financings, or potentially other capital sources, such as collaboration or licensing arrangements with third parties or other strategic transactions. There are no assurances that we will be successful in obtaining an adequate level of financing to support our business plans when needed on acceptable terms, or at all. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be or could be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our common stockholders. Debt financing and 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 collaboration or licensing arrangements with third parties or other strategic transactions, we may have to relinquish rights to our intellectual property, future revenue streams, research programs, or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise capital as and when needed, or on attractive terms, we may have to significantly delay, reduce, or discontinue the development and commercialization of our product candidates or scale back or terminate our pursuit of new in-licenses and acquisitions.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our products, we are unable to estimate the exact amount of our operating capital requirements. Our future funding requirements will depend on many factors, including the following:

- the timing, scope, progress and results of our preclinical studies and clinical trials for our current and future product candidates;
- the number, scope and duration of clinical trials required for regulatory approval of our current and future product candidates;
- the outcome, timing and cost of seeking and obtaining regulatory approvals from the FDA and comparable foreign regulatory authorities for our product candidates;
- the cost of manufacturing clinical and commercial supplies as well as scale up of our current and future product candidates;
- the increase in the number of our employees and expansion of our physical facilities to support growth initiatives;
- our ability to establish new, strategic collaborations, licensing or other arrangements;
- the cost of filing and prosecuting our patent applications, and maintaining and enforcing our patents and other intellectual property rights;
- the extent to which we acquire or in-license other product candidates and technologies;
- the cost of defending intellectual property disputes, including patent infringement actions brought by third parties against our product candidates;
- the timing of when we pay our operating expenses;
- the effect of competing technological and market developments;
- the costs and timing of future commercialization activities, including product manufacturing, marketing, sales and distribution, for any of our product candidates for which we receive marketing approval;
- the amount of revenue, if any, received from commercial sales of our product candidates, should any of our product candidates receive marketing approval;
- our implementation of various computerized informational systems and efforts to enhance operational systems;

- the costs associated with being a public company; and
- other factors, including economic uncertainty and geopolitical tensions, which may exacerbate the magnitude of the factors discussed above.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (369,523)	$ (255,078)
Net cash provided by (used in) investing activities	287,877	(113,790)
Net cash provided by financing activities	2,067	492,367
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (79,579)	$ 123,499

Operating Activities

Net cash used in operating activities was $369.5 million and $255.1 million for the years ended December 31, 2025 and 2024, respectively.

Net cash used in operating activities for the year ended December 31, 2025 was due to our net loss for the period of $243.3 million and changes in non-cash items totaling $144.0 million, partially offset by changes in operating assets and liabilities of $17.8 million. Non-cash items included $187.9 million related to gain on bargain purchase in connection with the ACELYRIN Merger and net accretion of discounts on marketable securities of $5.3 million, partially offset by $43.5 million related to stock-based compensation expense, $3.5 million related to depreciation and amortization, $1.7 million related to non-cash lease expense and $0.5 million related to impairment of long-lived assets. The changes in operating assets and liabilities primarily included a decrease of $17.2 million in other prepaid expenses and other assets, a decrease of $11.5 million in research and development prepaid expenses, an increase of $6.0 million in other accrued expenses and current liabilities, an increase of $4.1 million in deferred revenue, and an increase of $2.1 million in research and development accrued expenses, partially offset by an $8.6 million decrease in deferred tax liability, a decrease of $6.0 million in accounts payable, an increase of $5.5 million in other assets, non-current and a decrease of $3.2 million in operating lease liabilities.

Net cash used in operating activities for the year ended December 31, 2024 was due to our net loss for the period of $294.2 million, partially offset by changes in non-cash items totaling $24.4 million and changes in operating assets and liabilities of $14.8 million. Non-cash items included $19.5 million related to stock-based compensation expense, $5.4 million related to the change in fair value of the derivative liability and $3.2 million related to depreciation and amortization, partially offset by net accretion of discounts on marketable securities of $3.7 million. The changes in operating assets and liabilities primarily included an increase of $18.2 million in research and development accrued expenses, an increase of $8.5 million in accounts payable and a $3.5 million increase in other accrued expenses and current liabilities, partially offset by an increase of $10.8 million in research and development prepaid expenses, an increase of $2.9 million in other prepaid expenses and other assets and a decrease of $1.9 million in operating lease liabilities.

Investing Activities

Net cash provided by investing activities of $287.9 million for the year ended December 31, 2025, was related to maturities of marketable securities of $448.0 million and cash, cash equivalents and restricted cash acquired in connection with the ACELYRIN Merger of $49.7 million, partially offset by purchases of marketable securities of $209.2 million and by purchases of property and equipment of $0.7 million.

Net cash used in investing activities of $113.8 million for the year ended December 31, 2024, was related to purchases of marketable securities of $240.1 million and purchases of property and equipment of $1.7 million, partially offset by maturities of marketable securities of $128.0 million.

Financing Activities

Net cash provided by financing activities of $2.1 million for the year ended December 31, 2025 was primarily related to proceeds from the issuance of common stock under the 2024 ESPP (defined below) of $1.6 million and proceeds from issuance of common stock upon exercise of stock options of $0.5 million.

Net cash provided by financing activities of $492.4 million for the year ended December 31, 2024, included $258.5 million proceeds from the issuance of redeemable convertible preferred stock and derivative liability, net of offering costs, $193.3 million proceeds from initial public offering, net of underwriter discounts and commissions and other offering costs, $40.0 million proceeds from a private placement transaction and $0.6 million proceeds from issuance of common stock upon exercise of stock options.

Contractual Obligations and Commitments

Leases

We have operating lease arrangements for office and laboratory space in South San Francisco, California and office space in Southern California. As of December 31, 2025, we had total undiscounted lease payment obligations under non-cancelable leases of $8.5 million payable in the 12 months following December 31, 2025, and $44.5 million payable thereafter.

FronThera Contingent Consideration

On March 5, 2021, we entered into the FronThera Acquisition, and the transaction was accounted for as an asset acquisition. Under the agreement, we are obligated to pay contingent consideration of up to an aggregate of $120.0 million based on the achievement of specified clinical and approval milestones, for up to an aggregate of $70.0 million payable for clinical milestones, and for up to an aggregate of $50.0 million payable for approval milestones, including receipt of first commercialization approval in the United States or certain other jurisdictions, all related to technology acquired under the agreement. In the year ended December 31, 2022, we incurred and made a $37.0 million milestone payment for the first administration of envu to a patient enrolled in a Phase 2 clinical trial of envu, which was recorded in research and development expenses in the consolidated statement of operations and comprehensive loss. In July 2024, we met a milestone in connection with the first administration of envu to a patient enrolled in a Phase 3 clinical trial of envu and made a $23.0 million milestone payment in August 2024, which was recorded in research and development expenses in the consolidated statement of operations and comprehensive loss for the year ended December 31, 2024. No other milestones were achieved or were probable of being achieved as of December 31, 2025.

License and Commercialization Agreement with Pierre Fabre

Upon the closing of the Merger Agreement, we became the successor to ACELYRIN's rights and obligations under the Pierre Fabre Agreement. We received certain exclusive worldwide licenses with the right to sublicense certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. The license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a "PF Licensed Product"). The Pierre Fabre Agreement prohibits us from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

We are obligated to (i) make payments of up to $100.5 million upon the achievement of various development and regulatory milestones, (ii) make milestone payments of up to $390.0 million upon the achievement of certain commercial milestones, and (iii) pay tiered royalties in the high single-digit to low-teen percentages to Pierre Fabre on worldwide net sales in a given calendar year. Royalties will be payable for each PF Licensed Product in a given country during a period commencing upon the first commercial sale of such PF Licensed Product in such country and continuing until the latest of (a) 10 years after such first commercial sale, (b) expiration of last-to-expire valid claim in a licensed patent in such country and (c) expiration of regulatory exclusivity for such PF Licensed Product in such country. In the event we enter into a sublicense with a third party, we must also share with Pierre Fabre a percentage of any revenues from option fees, upfront payments, license maintenance fees, milestone payments or the like generated from the sublicense. Such

percentage may be between the high single-digits to the low thirties based on which stage of development of a PF Licensed Product the sublicense relates to.

Unless earlier terminated, the Pierre Fabre Agreement will continue on a PF Licensed Product-by-PF Licensed Product and country-by-country basis until there are no more royalty payments owed to Pierre Fabre on any PF Licensed Product thereunder. Either party may terminate the Pierre Fabre Agreement upon an uncured material breach, or upon the bankruptcy or insolvency of the other party. Pierre Fabre may also terminate the agreement if we or any of our affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. We may also terminate the Pierre Fabre Agreement with or without cause upon nine months' prior written notice, so long as there is no ongoing clinical trial for any PF Licensed Product.

As of December 31, 2025, no milestones were achieved or probable of being achieved.

Purchase Commitments

We enter into contracts in the normal course of business with suppliers, CROs, CMOs and clinical trial sites. Upon the closing of the ACELYRIN Merger, we became the successor to contracts with non-cancellable obligations under ACELYRIN contracts. The total value of non-cancellable obligations under contracts was $1.6 million as of December 31, 2025. This presentation of non-cancellable purchase obligations does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counterparties in the event of cancellation under the terms of our engagements.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K for additional information.

Critical Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"). The preparation of these consolidated financial statements requires us 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 expenses during the reporting period. On an ongoing basis, we evaluate our estimates and assumptions, including but not limited to those related to research and development expenses and accruals, valuation of acquired IPR&D intangible assets, revenue recognition and stock-based compensation expense. These estimates and assumptions are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates and assumptions could occur in the future. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Changes in estimates are reflected in reported results for the period in which they become known. Actual results may differ from these estimates under different assumptions or conditions.

Although our significant accounting policies are described in more detail in Note 2 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Research and Development Expenses and Accruals

Research and development costs are expensed as incurred. As part of the process of preparing our financial statements, we are required to estimate our research and development accrued expenses, including those related to clinical trials and manufacturing clinical and preclinical materials. This process involves reviewing open contracts and purchase orders and communicating with our applicable personnel to identify services that have been performed on our behalf and estimating

the level of service performed and the associated cost incurred for the services when we have not yet been invoiced or otherwise notified of actual costs. Our service providers invoice us in arrears, as well as on a pre-determined schedule or when contractual milestones are met. We make estimates of our research and development accrued expenses as of each balance sheet date in the consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of the estimates with the service providers and make adjustments if necessary. Examples of estimated research and development accrued expenses include fees paid to:

- vendors in connection with preclinical and clinical development activities;
- CROs in connection with clinical trials; and
- CMOs in connection with the process development and scale-up activities and the production of preclinical and clinical trial materials.

Costs for clinical trials and manufacturing activities are recognized based on an evaluation of our vendors' progress towards completion of specific tasks, using data such as participant enrollment, clinical site activations or information provided to us by our vendors regarding their actual costs incurred. Payments for these activities are based on the terms of individual contracts and payment timing may differ significantly from the period in which the services were performed. We determine accrual estimates through reports from and discussions with applicable personnel and outside service providers as to the progress or state of completion of studies, or the services completed. Our estimates of research and development accrued expenses as of each balance sheet date are based on the facts and circumstances known at the time. Costs that are paid in advance of performance are deferred as a prepaid expense and amortized over the service period as the services are provided.

Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in reporting amounts that are too high or too low in any particular period. To date, there have not been any material adjustments to our prior estimates of research and development accrued expenses. However, due to the nature of estimates, we cannot assure that we will not make changes to our estimates in the future as we become aware of additional information about the status or conduct of our clinical trials and other research activities.

Business Acquisitions, Including Intangible Assets, Goodwill and Contingent Consideration

We account for business combinations, as defined in Accounting Standards Codification ("ASC") Topic 805, *Business Combinations*, using the acquisition method of accounting, which generally requires that assets acquired, including IPR&D intangible assets, and liabilities assumed, be recorded at fair value on the consolidated balance sheets as of the acquisition date. The excess of the fair value of the purchase consideration over the fair value of net assets acquired, if any, is recorded as goodwill on the consolidated balance sheet. The excess of the fair value of net assets acquired over the fair value of the purchase consideration, if any, represents negative goodwill, or a gain on bargain purchase, which is recognized in the consolidated statement of operations as of the date of the acquisition.

Calculating the fair value of assets acquired and liabilities assumed requires us to make significant estimates and assumptions. As a result, we may record adjustments to the fair values within the measurement period, which may be up to one year from the acquisition date, with the corresponding offset to goodwill or a gain on bargain purchase.

Transaction costs associated with business combinations are expensed as they are incurred.

Intangible assets related to IPR&D projects acquired are considered to be indefinite-lived until abandonment or completion of the associated R&D efforts, which generally occurs when regulatory approval is obtained. Goodwill and indefinite-lived intangible assets are not amortized and, instead, are tested for impairment annually, in the fourth quarter, or more frequently if events or changes in circumstances indicate that it is more likely than not that the assets are impaired as required by ASC 350 *Intangibles – Goodwill and Other*. Such events and circumstances may include a significant change in our business climate, economic and industry trends, legal factors, negative operating performance indicators, significant competition or changes in strategy. We perform testing of indefinite-lived intangible assets, other than goodwill, at the

asset group level using a discounted cash flow model. If the carrying value exceeds the fair value, an impairment loss is recorded for that excess. We would also be required to reduce the carrying amounts of the related assets on our consolidated balance sheet. Determining the fair value of an indefinite-lived intangible asset group requires the application of judgment and involves the use of significant estimates and assumptions, including projections of future cash flows, which include estimated revenues, costs and probabilities of achieving technical and regulatory milestones, and discount rates, among other factors. We base our fair value estimates on assumptions we believe to be reasonable, but which are unpredictable and inherently uncertain. Actual future results may differ from the estimates. Development costs incurred after an acquisition are expensed as they are incurred.

Intangible assets with finite useful lives, which include completed IPR&D projects, are amortized over their estimated useful lives, primarily on a straight-line basis, and are also periodically reviewed for changes in facts or circumstances that may result in an impairment or in a reduction to the estimated useful life of the asset.

In determining the initial fair value of an intangible asset, or when quantitative analysis is required to determine any impairment, we usually use an income approach that discounts expected future cash flows to present value using a discount rate that is based on the estimated weighted-average cost of capital for comparable companies and represents the rate that market participants would use to value the intangible asset. These cash flow models require the use of Level 3 fair value measurements and inputs, including estimated revenues, costs and probabilities of technical and regulatory milestones, among other factors.

If we are required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events, then the estimated fair value of contingent consideration liabilities is recognized in the consolidated balance sheet as of the date of the acquisition. Each reporting period thereafter, we revalue these obligations and record increases or decreases in their fair value on the consolidated statements of operations until such time that the payment is made or obligations expire.

Revenue Recognition

We earn revenue from collaboration agreements that allow collaborators to develop, manufacture and commercialize product candidates. Collaboration revenue is recognized in accordance with ASC Topic 606, *Revenue from Contracts with Customers* ("ASC 606"). Arrangements with collaborators may include intellectual property licenses, research and development services, manufacturing services for clinical and commercial supply and participation in joint steering committees.

We recognize collaboration revenue in an amount that reflects the consideration that we expect to receive in exchange for those goods or services when our collaborator, or customer, obtains control of promised goods or services. We follow a five-step approach: (i) identify the contract 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, and (v) recognize revenue when (or as) the customer obtains control of the product or service.

At contract inception, once the contract is determined to be within the scope of ASC 606, we assess the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources and (ii) are separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet the requirements of a performance obligation.

We determine the transaction price based on the amount of consideration we are entitled to receive in exchange for the transfer of control of a product or a service to the customer. Consideration may be fixed, variable, or a combination of both. Payments to us under these arrangements typically include one or more of the following: non-refundable upfront payments, reimbursement for research services, payments for clinical supplies, research, development or regulatory milestone payments, profit-sharing arrangements, and royalty and commercial sales milestone payments. Variable consideration, such as performance-based milestones, are included in the total consideration if we expect to receive such consideration and if it is probable that the inclusion of the variable consideration will not result in a significant reversal in

the cumulative amount of revenue recognized under the arrangement. We account for cost reimbursements included in the transaction price using the expected value method. We exclude sales-based royalty and milestone payments from the total consideration we expect to receive until the underlying sales occur because the license to our intellectual property is deemed to be the predominant item to which the royalties or milestones relate as it is the primary driver of value in the collaboration arrangements.

We then allocate the transaction price to each distinct performance obligation based on the relative standalone selling price. Key assumptions to determine the standalone selling price may include forecasted revenues, development timelines, probabilities of technical and regulatory success, and the expected level of effort for research and development services. We recognize revenue associated with each performance obligation as the control over the promised goods or services transfer to our collaborators which occurs either at a point in time or over time. If control transfers over time, revenue is recognized by using a method of measuring progress that best depicts the transfer of goods or services. We evaluate the measure of progress and related inputs each reporting period and any resulting adjustments to revenue are recorded on a cumulative catch-up basis. Consideration allocated to options that include material rights is deferred until the options are exercised or expire.

Stock-Based Compensation Expense

We account for stock-based compensation expense in accordance with ASC Topic 718, *Compensation-Stock Compensation* ("ASC 718"). We grant stock-based awards to employees, directors and non-employee consultants in the form of stock options and restricted stock units ("RSUs") to purchase shares of our common stock. Compensation expense for stock options with service-based vesting conditions is measured at the fair value of the award on the grant date and is recognized over the requisite service period, which is generally the vesting period, using the straight-line method. We estimate the fair value of each stock option with service-based vesting on the date of grant using the Black-Scholes option pricing model. This model requires the use of subjective assumptions to determine the fair value of each stock-based award, including:

- *Fair value of common stock.* See the subsection titled "—Determination of Fair Value of Common Stock" below.

- *Expected term.* The expected term represents the weighted-average period the stock options are expected to remain outstanding and is based on the options' vesting terms and contractual terms as we do not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

- *Expected volatility.* As the Company did not have sufficient trading history of its common stock, the expected volatility was estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period equal to the expected term of the stock option grants. The comparable industry peers were chosen based on their size, stage of their life cycle or area of specialty. We will continue to apply this process until enough historical information regarding the volatility of our stock price becomes available.

- *Risk-free interest rate.* The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.

- *Expected dividend yield.* We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

We have also granted stock options with graded vesting based on market, service and performance conditions. At the grant date, the fair value of these stock options was estimated using a Monte Carlo simulation model, which uses a distribution of potential outcomes over the vesting period. The assumptions utilized in the calculation included our expected common stock price, expected volatility, risk-free rate and expected term. Stock-based compensation expense for these awards is recognized on a straight-line basis over the requisite service period, which is the longer of the explicit service period of the service condition and the derived service period of the market condition, as determined for each separately vesting portion of the awards as if each award was, in substance, multiple awards.

Stock-based compensation expense related to stock purchase rights under our 2024 Employee Stock Purchase Plan (the "2024 ESPP") is measured based on grant date at fair value using the Black-Scholes option-pricing model. The model requires us to make a number of assumptions, including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield. Stock-based compensation expense is recognized on a straight-line basis over the offering period.

We account for award forfeitures as they occur and classify stock-based compensation expense in our consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's salary or services costs are classified.

Off-Balance Sheet Arrangements

During the periods presented we did not have, nor do we currently have, any off-balance sheet arrangements as defined in the rules and regulations of the Securities and Exchange Commission ("SEC").

JOBS Act Transition Period and Smaller Reporting Company Status

We are an "emerging growth company" as defined in the JOBS Act. Under the JOBS Act, an emerging growth company can take advantage of the extended transition period for complying with new or revised accounting standards and delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to avail ourselves of this exemption from complying with new or revised accounting standards and, therefore, will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. As a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation exemptions to the requirements for (i) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (ii) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (A) following the fifth anniversary of the completion of our IPO, (B) in which we have total annual gross revenues of at least $1.235 billion or (C) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our common stock and non- voting common stock that is held by non-affiliates exceeds $700.0 million as of the prior June 30th, or (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

We are also a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act, meaning that the market value of our common stock and non-voting common stock held by non-affiliates was less than $250.0 million as of June 30, 2025. We may continue to be a smaller reporting company if either (i) the market value of our common stock and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter or (ii) our annual revenue is less than $100.0 million during the most recently completed fiscal year and the market value of our common stock and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. If we are a smaller reporting company at the time we cease to be an emerging growth company, we may continue to rely on exemptions from certain disclosure requirements that are available to smaller reporting companies. Specifically, as a smaller reporting company we may choose to present only the two most recent fiscal years of audited consolidated financial statements in our Annual Report on Form 10-K and, similar to emerging growth companies, smaller reporting companies have reduced disclosure obligations regarding executive compensation.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Interest Rate Risk

The primary objectives of our investment activities are to ensure liquidity and to preserve capital. We are exposed to market risks related to changes in interest rates of our cash equivalents and marketable securities. However, due to the nature of these cash equivalents and marketable securities, we do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have had a material effect on our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Foreign Currency Exchange Risk

All of our employees and our operations are currently located in the United States, and our expenses are generally denominated in U.S. dollars. However, we do utilize certain CRO and CMO vendors outside of the United States for our clinical trials and product development and manufacturing. As such, our expenses are denominated in both U.S. dollars and foreign currencies. Therefore, our operations are and will continue to be subject to fluctuations in foreign currency exchange rates. To date, foreign currency transaction gains and losses have not been material to our consolidated financial statements, and we have not had a formal hedging program with respect to foreign currency. We do not believe that a hypothetical 10% increase or decrease in exchange rates during any of the periods presented would have had a material effect on our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Effects of Inflation

Inflation generally affects us by increasing our cost of labor and research and development costs. We do not believe that inflation had a material effect on our business, results of operations, or financial condition, or on our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Item 8. Financial Statements and Supplementary Data

ALUMIS INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Board of Directors and Stockholders of Alumis Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Alumis Inc. and its subsidiaries (the "Company") as of December 31, 2025 and 2024, and the related consolidated statements of operations and comprehensive loss, of redeemable convertible preferred stock and stockholders' equity (deficit) 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.

/s/ PricewaterhouseCoopers LLP
San Jose, California
March 19, 2026

We have served as the Company's auditor since 2022.

ALUMIS INC.
CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share amounts)	December 31, 2025	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 89,670	$ 169,526
Restricted cash	82	—
Marketable securities	218,831	118,737
Research and development prepaid expenses	2,909	13,424
Other prepaid expenses and current assets	6,740	4,501
Total current assets	318,232	306,188
Restricted cash, non-current	1,301	1,106
Property and equipment, net	18,190	20,968
Intangible assets	50,959	—
Operating lease right-of-use assets, net	16,971	12,723
Other assets, non-current	6,287	7
Total assets	$ 411,940	$ 340,992
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,106	$ 9,624
Research and development accrued expenses	34,781	29,149
Deferred revenue, current	1,458	—
Other accrued expenses and current liabilities	22,303	10,580
Operating lease liabilities, current	4,670	1,557
Total current liabilities	73,318	50,910
Operating lease liabilities, non-current	32,244	29,165
Deferred revenue, non-current	2,611	—
Deferred tax liability	2,140	—
Share repurchase liability	123	813
Other liabilities, non-current	207	—
Total liabilities	110,643	80,888
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 50,000,000 shares authorized, zero shares issued and outstanding as of December 31, 2025 and December 31, 2024	—	—
Common stock, voting, $0.0001 par value; 492,815,092 voting shares authorized as of December 31, 2025 and December 31, 2024; 99,084,365 and 47,222,419 voting shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	9	4
Common stock, non-voting, $0.0001 par value; 7,184,908 non-voting shares authorized as of December 31, 2025 and December 31, 2024; 5,622,408 and 7,184,908 non-voting shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively	1	1
Additional paid-in capital	1,202,975	918,610
Accumulated other comprehensive income (loss)	188	40
Accumulated deficit	(901,876)	(658,551)
Total stockholders' equity	301,297	260,104
Total liabilities and stockholders' equity	$ 411,940	$ 340,992

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

ALUMIS INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share and per share amounts)	Year Ended December 31, 2025	2024
Revenue:		
License revenue	$ 17,389	$ —
Collaboration revenue	6,661	—
Total revenue	24,050	—
Operating expenses:		
Research and development expenses, including related party expenses of $1,144 and $912 for the years ended December 31, 2025 and 2024, respectively	385,998	265,554
General and administrative expenses	91,856	35,200
Total operating expenses	477,854	300,754
Loss from operations	(453,804)	(300,754)
Other income (expense):		
Gain on bargain purchase	187,907	—
Interest income	14,180	12,020
Change in fair value of derivative liability	—	(5,406)
Other income (expenses), net	(169)	(93)
Total other income (expense), net	201,918	6,521
Net loss before income taxes	(251,886)	(294,233)
Income tax benefit	8,561	—
Net loss	$ (243,325)	$ (294,233)
Other comprehensive income (loss):		
Unrealized gain (loss) on marketable securities, net	148	38
Total comprehensive loss	$ (243,177)	$ (294,195)
Net loss per share attributable to common stockholders, basic and diluted	$ (2.86)	$ (10.38)
Weighted-average shares of common stock outstanding, basic and diluted	85,029,624	28,341,866

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

ALUMIS INC.
CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)

(in thousands, except share amounts)	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2023	**85,960,088**	**$ 375,370**	**2,675,979**	**$ 1**	**$ 25,055**	**$ 2**	**$ (364,318)**	**$ (339,260)**
Issuance of Series C redeemable convertible preferred stock in March 2024 for cash, net of derivative liability of $8,913 and offering costs of $382	41,264,891	120,205	—	—	—	—	—	—
Issuance of Series C redeemable convertible preferred stock in May 2024 for cash and settlement of the derivative liability of $14,319, net of offering costs of $157	41,264,892	143,662	—	—	—	—	—	—
Issuance of voting common stock upon initial public offering, net of underwriting discounts and commissions and other offering costs of $16,684	—	—	13,125,000	1	193,315	—	—	193,316
Issuance of voting common stock in private placement transaction	—	—	2,500,000	—	40,000	—	—	40,000
Conversion and redesignation of redeemable convertible preferred stock into 28,855,656 shares of voting common stock and 7,184,908 shares of non-voting common stock in connection with initial public offering	(168,489,871)	(639,237)	36,040,564	3	639,234	—	—	639,237
Issuance of common stock upon exercise of stock options and early exercise of stock options	—	—	72,201	—	375	—	—	375
Vesting of early exercised stock options	—	—	—	—	1,154	—	—	1,154
Vesting of restricted shares of common stock	—	—	—	—	20	—	—	20
Repurchase of unvested early exercised restricted common stock	—	—	(6,417)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	19,457	—	—	19,457
Other comprehensive income (loss), net	—	—	—	—	—	38	—	38
Net loss	—	—	—	—	—	—	(294,233)	(294,233)
Balance as of December 31, 2024	**—**	**—**	**54,407,327**	**5**	**918,610**	**40**	**(658,551)**	**260,104**
Issuance of common stock and equity awards in connection with the ACELYRIN merger	—	—	48,653,549	5	238,072	—	—	238,077
Issuance of common stock upon vesting of RSUs	—	—	1,201,282	—	—	—	—	—
Issuance of common stock under the 2024 ESPP	—	—	388,739	—	1,595	—	—	1,595
Issuance of common stock upon exercise of stock options and early exercise of stock options	—	—	57,659	—	501	—	—	501
Vesting of early exercised stock options	—	—	—	—	671	—	—	671
Vesting of restricted shares of common stock	—	—	—	—	2	—	—	2
Repurchase of unvested early exercised stock options	—	—	(1,783)	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	43,524	—	—	43,524
Other comprehensive income (loss), net	—	—	—	—	—	148	—	148
Net loss	—	—	—	—	—	—	(243,325)	(243,325)
Balance as of December 31, 2025	**—**	**$ —**	**104,706,773**	**$ 10**	**$ 1,202,975**	**$ 188**	**$ (901,876)**	**$ 301,297**

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

ALUMIS INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended December 31, 2025	2024
Cash flows from operating activities		
Net loss	$ (243,325)	$ (294,233)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation	43,524	19,457
Net accretion of discounts on marketable securities	(5,298)	(3,685)
Depreciation and amortization	3,496	3,152
Non-cash lease expense	1,701	60
Loss on disposal of fixed assets	—	5
Change in fair value of derivative liability	—	5,406
Gain on bargain purchase in connection with the ACELYRIN Merger	(187,907)	—
Impairment of long-lived assets	529	—
Changes in operating assets and liabilities:		
Research and development prepaid expenses	11,473	(10,763)
Other prepaid expenses and other assets	17,229	(2,870)
Other assets, non-current	(5,535)	—
Accounts payable	(6,036)	8,506
Deferred revenue	4,069	—
Research and development accrued expenses	2,087	18,203
Other accrued expenses and current liabilities	6,036	3,542
Operating lease liabilities	(3,212)	(1,858)
Other liabilities, non-current	207	—
Deferred tax liability	(8,561)	—
Net cash used in operating activities	(369,523)	(255,078)
Cash flows from investing activities		
Maturities of marketable securities	447,955	128,000
Purchases of marketable securities	(209,167)	(240,058)
Purchases of property and equipment	(653)	(1,732)
Cash, cash equivalents and restricted cash acquired in connection with the ACELYRIN Merger	49,742	—
Net cash provided by (used in) investing activities	287,877	(113,790)
Cash flows from financing activities		
Proceeds from issuance of redeemable convertible preferred stock and derivative liability, net of issuance costs	—	258,461
Proceeds from initial public offering, net of underwriter discounts and commissions and other offering costs	—	193,316
Proceeds from a private placement transaction	—	40,000
Proceeds from issuance of common stock upon exercise of stock options	489	596
Repurchase of common stock shares issued upon early exercised restricted common stock	(17)	(6)
Proceeds from issuance of common stock under the 2024 ESPP	1,595	—
Net cash provided by financing activities	2,067	492,367
Net (decrease) increase in cash, cash equivalents and restricted cash	(79,579)	123,499
Cash, cash equivalents and restricted cash at beginning of period	170,632	47,133
Cash, cash equivalents and restricted cash at end of period	$ 91,053	$ 170,632
Supplemental disclosures:		
Conversion of 168,489,871 shares of redeemable convertible preferred stock upon the closing of initial public offering	$ —	$ 639,237
Equity consideration transferred in connection with the ACELYRIN Merger	$ 238,077	$ —
Vesting of early exercised stock options and unvested restricted shares of common stock	$ 673	$ 1,174
Right-of-use assets obtained in exchange for operating lease liabilities	$ 1,776	$ —
Recognition of derivative liability upon issuance of redeemable convertible preferred stock	$ —	$ 8,913
Settlement of derivative liability upon issuance of redeemable convertible preferred stock	$ —	$ (14,319)
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	$ 89,670	$ 169,526
Restricted cash	82	—
Restricted cash, non-current	1,301	1,106
Total cash, cash equivalents and restricted cash	$ 91,053	$ 170,632

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

1. Organization and Nature of the Business

Organization and Business

Alumis Inc. (the "Company") is a clinical stage biopharmaceutical company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines for autoimmune disorders. The Company leverages its proprietary precision data analytics platform, biological insights, and a team of experts with deep experience in precision medicine drug discovery, development, and immunology, in its mission to create medicines that significantly improve the lives of patients by replacing broad immunosuppression with targeted therapies.

The Company was founded on January 29, 2021, as a Delaware corporation under the name FL2021-001, Inc. FL2021-001, Inc.'s name was changed to Esker Therapeutics, Inc. on March 8, 2021, and to Alumis Inc. on January 6, 2022. The Company is headquartered in South San Francisco, California.

As of December 31, 2023, the Company had two wholly owned subsidiaries, FronThera U.S. Holdings, Inc. and FronThera U.S. Pharmaceuticals LLC. FronThera U.S. Holdings, Inc. was dissolved on April 8, 2024 and FronThera U.S. Pharmaceuticals LLC was dissolved on March 14, 2024. These subsidiaries did not have operations during the year ended December 31, 2024.

As of December 31, 2025, the Company had two wholly owned subsidiaries, ACELYRIN, Inc. ("ACELYRIN"), a Delaware corporation incorporated on July 27, 2020 and its wholly owned subsidiary, WH2, LLC. Arrow Merger Sub, Inc. ("Merger Sub"), the Company's wholly owned subsidiary incorporated in January 2025, was merged with and into ACELYRIN in May 2025.

Reverse Stock Split

On June 19, 2024, the board of directors approved, and on June 20, 2024, the Company effected, a reverse stock split of the shares of the Company's outstanding common stock at a ratio of 1-for-4.675 (the "Reverse Stock Split"). The number of authorized shares and par value per share were not adjusted as a result of the Reverse Stock Split. All references to shares, options to purchase common stock, share amounts, per share amounts, and related information contained in the consolidated financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented. The shares of common stock underlying outstanding stock options and other equity instruments were proportionately reduced and the respective exercise prices, if applicable, were proportionately increased in accordance with the terms of the agreements governing such securities. In addition, the conversion ratios for each series of the Company's redeemable convertible preferred stock, which were automatically convertible into shares of common stock upon the closing of the Company's IPO of common stock, were proportionally adjusted.

IPO and Concurrent Private Placement

On July 1, 2024, the Company completed its IPO, pursuant to which it issued and sold 13,125,000 shares of its common stock at $16.00 price per share to the public. Net proceeds from the IPO were $193.3 million, after deducting underwriting discounts and commissions and other offering costs totaling $16.7 million. On July 17, 2024, in connection with the IPO, an existing investor and a holder of more than 5% of the Company's capital stock, purchased an additional 2,500,000 shares of the Company's common stock at the IPO price per share for total gross and net proceeds of $40.0 million in the Concurrent Private Placement.

Immediately prior to the closing of the IPO on July 1, 2024, all of the shares of the Company's redeemable convertible preferred stock then outstanding converted into 28,855,656 shares of Class A common stock and 7,184,908 shares of Class B common stock at a 1-for-4.675 conversion ratio (the "Preferred Stock Conversion"). All outstanding Class A common stock shares and all outstanding Class B common stock shares were redesignated immediately thereafter into the same number of shares of voting common stock and non-voting common stock, respectively. Unless the context otherwise requires a different meaning, all references to "common stock" in these notes refers to the Company's voting common

stock and non-voting common stock combined.

ACELYRIN Merger

On February 6, 2025, the Company entered into an Agreement and Plan of Merger, and, on April 20, 2025, the Company entered into an Amendment to Agreement and Plan of Merger (collectively the "Merger Agreement") with ACELYRIN and Merger Sub, a Delaware corporation and a direct wholly owned subsidiary of the Company. Under the terms of the Merger Agreement, Merger Sub merged with and into ACELYRIN, with ACELYRIN continuing as a direct wholly owned subsidiary of the Company (the "ACELYRIN Merger"). The Merger Agreement was approved by the disinterested directors on the Company's board of directors and the board of directors of ACELYRIN and was approved by the stockholders of each company on May 13, 2025. On May 21, 2025, the Company completed the ACELYRIN Merger with ACELYRIN for a purchase consideration of approximately $238.1 million that included the issuance of 48,653,549 shares of the Company's common stock and the fair value of replacement awards attributable to pre-combination services, to acquire net assets with a fair value of approximately $426.0 million. See Note 3 for additional information.

Public Offering of Common Stock

On January 7, 2026, the Company entered into the Underwriting Agreement with the Underwriters, relating to the issuance and sale in a public offering of 17,650,000 shares of the Company's common stock at a price of $17.00 per share. In addition, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to 2,647,500 additional shares of common stock at the public offering price, less the underwriting discounts and commissions, which was exercised in full on January 8, 2026. On January 9, 2026, the offering closed and the Company received net proceeds of $324.4 million, after deducting underwriting discounts and commissions.

The offering was made pursuant to a shelf registration statement on Form S-3 (File No. 333-288510) that was filed with the SEC on July 3, 2025 and declared effective by the SEC on August 19, 2025, and related prospectus and prospectus supplement thereunder.

Liquidity

The Company has incurred negative operating cash flows and significant losses from operations since its inception. For the years ended December 31, 2025 and 2024, the Company incurred net losses of $243.3 million and $294.2 million, respectively. Cash used in operating activities was $369.5 million and $255.1 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company had an accumulated deficit of $901.9 million.

The Company has historically funded its operations primarily through the issuance of common stock, including in connection with the ACELYRIN Merger, its IPO and Concurrent Private Placement, the issuance of redeemable convertible preferred stock and convertible promissory notes in private placements, payments received under the Kaken Collaboration Agreement and, most recently, the public offering of common stock which closed on January 9, 2026. The Company expects to continue to incur substantial losses for the foreseeable future, and its ability to achieve and sustain profitability will depend on the successful development, approval, and commercialization of any product candidates it may develop, and on the achievement of sufficient revenue to support its cost structure. The Company may never achieve profitability and, unless and until it does, it will need to continue to raise additional capital. The Company believes that, based on its current operating plan, its existing cash, cash equivalents and marketable securities of $308.5 million as of December 31, 2025, as well as net proceeds of $324.4 million, after deducting underwriting discounts and commissions from the public offering of common stock, which closed on January 9, 2026, will be sufficient to meet its operating and capital requirements for at least 12 months from the date of issuance of these consolidated financial statements.

The Company will need to raise significant additional capital to fund ongoing research and development activities and maintain future operations. The Company's management continuously monitors and, where necessary, may reduce its operating expenses in response to its clinical development progress and its ability and need to raise additional capital

through a combination of public and private equity, debt financings, strategic alliances and licensing arrangements. For example, should any of the Company's ongoing trials not meet its clinical development objectives, the Company may scale back or discontinue related activities and reallocate its working capital to extend its ability to meet its operating and capital requirements. The Company's ability to access capital when needed is not assured and, if capital is not available to the Company when, and in the amounts, needed, on the terms which are favorable, the Company could be required to delay, scale back, or abandon some or all of its planned development programs and other operations, which could materially harm the Company's business, financial condition and results of operations.

2. Summary of Significant Accounting Policies and Basis of Presentation

Basis of Presentation

The accompanying consolidated financial statements and accompanying notes have been prepared in accordance with U.S. GAAP. The Company's consolidated financial statements include the accounts of its subsidiaries, and all intercompany transactions were eliminated. The Company's consolidated financial statements as of and for the year ended December 31, 2025, include the accounts of its subsidiaries ACELYRIN and WH2, LLC after the closing of the ACELYRIN Merger, and the accounts of Merger Sub from its incorporation in January 2025 until the ACELYRIN Merger. WH2, LLC has not had any operations or any balances since the closing of the ACELYRIN Merger. The Company's consolidated financial statements as of and for the year ended December 31, 2024, included the accounts of FronThera U.S. Holdings, Inc. and FronThera U.S. Pharmaceuticals LLC, two wholly owned subsidiaries, prior to their dissolution.

Any reference in these notes to applicable guidance is meant to refer to the authoritative U.S. GAAP as found in the ASC and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Use of Estimates

The preparation of financial statements in conformity with U.S. 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 period.

On an ongoing basis, the Company evaluates estimates and assumptions, including but not limited to those related to research and development expenses, valuation of acquired IPR&D intangible assets, revenue recognition, and stock-based compensation expense. Management bases its estimates on historical experience and on various other assumptions that are believed 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. Actual results may differ materially from those estimates.

Segment and Geographical Information

The Company operates and manages its business as one reportable and operating segment, which is the business of researching and developing medicines for autoimmune disorders. The chief executive officer, who is the chief operating decision maker ("CODM"), reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance (see Note 16 for additional information). All of the Company's long-lived assets are located in the United States.

Concentration of Credit Risk

Financial instruments, which potentially subject the Company to concentration of credit risk, consist primarily of cash and cash equivalents, investments in marketable securities, accounts receivable and restricted cash. The Company maintains bank deposits in federally insured financial institutions and certain of these deposits exceed federally insured limits. To date, the Company has not experienced any losses on its deposits of cash and periodically evaluates the creditworthiness of the financial institutions at which its bank deposits are maintained.

The Company also invests in money market funds, U.S. Treasury obligations, commercial paper, corporate debt obligations, supranational debt obligations, government development bank obligations and Federal agency obligations, which can be subject to certain credit risks. The Company mitigates the risks by limiting its exposure to any one issuer and monitoring the ongoing creditworthiness of the financial institutions and issuers. The Company has not experienced any loss of principal on its financial instruments.

The Company considers a customer to be significant when revenues from that customer represent 10% or more of total revenues. All of the Company's revenues are currently earned under its license and collaboration agreement with Kaken. As a result, the Company is subject to customer concentration risk. To date, the Company has not incurred any credit losses in connection with the Kaken Collaboration Agreement.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the Company's ability to advance the development of its proprietary precision data analytics platform, timing and ability to advance its product candidates through preclinical and clinical development; costs and timelines associated with the manufacturing of clinical supplies; regulatory approval, market acceptance of, and reimbursement for, any product candidates the Company may develop; performance of third-party vendors; competition from pharmaceutical or other biotechnology companies with greater financial resources or expertise; protection of intellectual property; litigation or claims against the Company based on intellectual property or other factors; and its ability to attract and retain employees necessary to support its growth.

The Company's business and results of operations may be affected by worldwide economic conditions, which may continue to be impacted by global macroeconomic challenges and uncertainty in the markets, including international trade policies and tariffs, severely diminished liquidity and credit availability, rising inflation and monetary supply shifts, rising interest rates, labor shortages, declines in consumer confidence, declines in economic growth, increases in unemployment rates, recession risks and uncertainty about economic and geopolitical stability (for example, related to the evolving U.S. and ex-U.S. tariff landscape). These worldwide economic conditions have continued throughout 2025 and may negatively impact the Company's business, financial position and results of operations.

Business Acquisitions, Including Intangible Assets, Goodwill and Contingent Consideration

The Company accounts for business combinations, as defined in ASC Topic 805, *Business Combinations*, using the acquisition method of accounting, which generally requires that assets acquired, including IPR&D intangible assets, and liabilities assumed, be recorded at fair value on the consolidated balance sheet as of the acquisition date. The excess of the fair value of the purchase consideration over the fair value of net assets acquired, if any, is recorded as goodwill on the consolidated balance sheet. The excess of the fair value of net assets acquired over the fair value of the purchase consideration, if any, represents negative goodwill, or a gain on bargain purchase, which is recognized in the consolidated statement of operations as of the date of the acquisition.

Calculating the fair value of assets acquired and liabilities assumed requires the Company to make significant estimates and assumptions. As a result, the Company may record adjustments to the fair values within the measurement period, which may be up to one year from the acquisition date, with the corresponding offset to goodwill or a gain on bargain purchase.

Transaction costs associated with business combinations are expensed as they are incurred.

Intangible assets related to IPR&D projects acquired are considered to be indefinite-lived until abandonment or completion of the associated R&D efforts, which generally occurs when regulatory approval is obtained. Goodwill and indefinite-lived intangible assets are not amortized and, instead, are tested for impairment annually, in the fourth quarter, or more frequently if events or changes in circumstances indicate that it is more likely than not that the assets are impaired as

required by ASC 350 *Intangibles - Goodwill and Other*. Such events and circumstances may include a significant change in the Company's business climate, economic and industry trends, legal factors, negative operating performance indicators, significant competition or changes in strategy. The Company performs testing of indefinite-lived intangible assets, other than goodwill, at the asset group level using a discounted cash flow model. If the carrying value exceeds the fair value, an impairment loss is recorded for that excess. The Company would also be required to reduce the carrying amounts of the related assets on its consolidated balance sheet. Determining the fair value of an indefinite-lived intangible asset group requires the application of judgment and involves the use of significant estimates and assumptions, including projections of future cash flows, which include estimated revenues, costs and probabilities of achieving technical and regulatory milestones, and discount rates, among other factors. The Company bases its fair value estimates on assumptions it believes to be reasonable, but which are unpredictable and inherently uncertain. Actual future results may differ from the estimates. Development costs incurred after an acquisition are expensed as they are incurred.

Intangible assets with finite useful lives, which include completed IPR&D projects, are amortized over their estimated useful lives, primarily on a straight-line basis, and are also periodically reviewed for changes in facts or circumstances that may result in an impairment or in a reduction to the estimated useful life of the asset.

In determining the initial fair value of an intangible asset, or when quantitative analysis is required to determine any impairment, the Company usually uses an income approach that discounts expected future cash flows to present value using a discount rate that is based on the estimated weighted-average cost of capital for comparable companies and represents the rate that market participants would use to value the intangible asset. These cash flow models require the use of Level 3 fair value measurements and inputs, including estimated revenues, costs and probabilities of technical and regulatory milestones, among other factors.

If the Company is required to pay future consideration that is contingent upon the achievement of specified development, regulatory approval or sales-based milestone events, then the estimated fair value of contingent consideration liabilities is recognized in the consolidated balance sheet as of the date of the acquisition. Each reporting period thereafter, the Company revalues these obligations and records increases or decreases in their fair value on the consolidated statements of operations until such time that the payment is made or obligations expire. See Note 3 for additional information.

Collaboration Arrangements and Revenue Recognition

The Company earns revenue from collaboration agreements that allow collaborators to develop, manufacture and commercialize product candidates. Arrangements with collaborators may include intellectual property licenses, research and development services, manufacturing services for clinical and commercial supply and participation in joint steering committees. At the inception of an agreement, the Company evaluates if an agreement is a collaborative arrangement within the scope of ASC 808, *Collaborative Arrangements* ("ASC 808"). For collaborative arrangements that fall within the scope of ASC 808, the Company first determines which elements of the collaboration are deemed to be a performance obligation with a customer within the scope of ASC 606. For elements of collaboration arrangements that are accounted for pursuant to ASC 808 and are not subject to the guidance in ASC 606, the Company applies the revenue recognition model under ASC 606 or other guidance, as deemed appropriate.

Under ASC 606, the Company recognizes revenue in an amount that reflects the consideration that the Company expects to receive in exchange for those goods or services when its collaborator, or customer, obtains control of promised goods or services. The Company follows a five-step approach: (i) identify the contract 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 and (v) recognize revenue when (or as) the customer obtains control of the product or service.

The Company assesses the goods or services promised within the contract to determine whether each promised good or service is a performance obligation. Performance obligations are promises in a contract to transfer a distinct good or service to the customer that (i) the customer can benefit from on its own or together with other readily available resources and (ii) are separately identifiable from other promises in the contract. Goods or services that are not individually distinct performance obligations are combined with other promised goods or services until such combined group of promises meet

the requirements of a performance obligation.

The Company determines the transaction price based on the amount of consideration the Company is entitled to receive in exchange for the transfer of control of a product or a service to the customer. Consideration may be fixed, variable, or a combination of both. Payments to the Company under these arrangements typically include one or more of the following: non-refundable upfront payments, reimbursement for research services, payments for clinical supplies, research, development or regulatory milestone payments, profit-sharing arrangements, and royalty and commercial sales milestone payments. Variable consideration, such as performance-based milestones, are included in the total consideration if the Company expects to receive such consideration and if it is probable that the inclusion of the variable consideration will not result in a significant reversal in the cumulative amount of revenue recognized under the arrangement. The Company accounts for cost reimbursements included in the transaction price using the expected value method. The Company excludes sales-based royalty and milestone payments from the total consideration it expects to receive until the underlying sales occur because the license to its intellectual property is deemed to be the predominant item to which the royalties or milestones relate as it is the primary driver of value in the collaboration arrangements.

The Company then allocates the transaction price to each distinct performance obligation based on the relative standalone selling price. Key assumptions to determine the standalone selling price may include forecasted revenues, development timelines, probabilities of technical and regulatory success, and the expected level of effort for research and development services. The Company recognizes revenue associated with each performance obligation as the control over the promised goods or services transfer to its collaborators which occurs either at a point in time or over time. If control transfers over time, revenue is recognized by using a method of measuring progress that best depicts the transfer of goods or services. The Company evaluates the measure of progress and related inputs each reporting period and any resulting adjustments to revenue are recorded on a cumulative catch-up basis. Consideration allocated to options that include material rights is deferred until the options are exercised or expire.

The Company records amounts as accounts receivable when the right to consideration is deemed unconditional. Consideration received that does not meet the requirements to satisfy ASC 606 revenue recognition criteria is recorded as deferred revenue in the consolidated balance sheets, classified as either current (less than 12 months) or non-current (more than 12 months) deferred revenue based on the Company's best estimate of when such revenue will be recognized. See Note 7 for additional information.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Restricted Cash

Restricted cash represents security deposits in the form of letters of credit issued in connection with the Company's leases (see Note 6 for additional information).

Marketable Securities

Marketable securities may consist of money market funds, U.S. Treasury obligations, commercial paper, corporate debt obligations, supranational debt obligations, government development bank obligations and Federal agency obligations with original maturities of more than three months at the time of purchase. As the Company's entire investment portfolio is considered available for use in current operations, the Company classifies all marketable securities as available-for-sale and as current assets, even though the stated maturity may be more than one year from the current balance sheet date. Marketable securities are carried at fair value, with the change in fair value reported as unrealized gains or losses in accumulated other comprehensive income (loss), which is a separate component of stockholders' equity (deficit) in the consolidated balance sheets.

The amortized cost of marketable securities is adjusted for amortization of premiums and accretion of discounts to maturity, which is included in interest income in the consolidated statements of operations and comprehensive loss. Realized gains and losses on the sale of securities are determined by specific identification of each security's cost basis. The Company regularly reviews its investment portfolio to determine if any security is impaired, which would require it to record an allowance for credit losses or an impairment charge in the period any such determination is made. In making this judgment, the Company evaluates, among other things, the extent to which the fair value of a security is less than its amortized cost, its intent to sell or whether it is more likely than not that the Company will be required to sell the security before recovery of its amortized cost basis, the financial condition of the issuer and any changes thereto, and, as necessary, the portion of a decline in fair value that is credit-related. This assessment could change in the future due to new developments or changes in assumptions related to any particular security. Realized gains and losses, allowances for credit losses and impairments on available-for-sale marketable securities, if any, are recorded in the consolidated statements of operations and comprehensive loss.

Fair Value Measurement

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. The carrying amounts of prepaid expenses, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to their short-term maturities. Financial instruments, such as money market funds, marketable securities and derivative liabilities are measured at fair value at each reporting date (see Note 4 for additional information).

Recoverable Value-Added Tax

The Company conducts clinical trials in several European and Asian countries that can result in value-added tax ("VAT") assessments based on the transfer of products across borders including production, packaging and distribution of clinical materials. VAT is a national tax that is levied at each stage of production and can vary by jurisdiction. When a company is not VAT-registered in a country, VAT is due when goods enter a country and is not considered reclaimable. When the Company becomes VAT-registered and establishes a pattern of VAT recoverability from taxing authorities in a certain country, the Company will record aggregate balances recoverable in other prepaid expenses and current assets in the consolidated balance sheets. The Company reviews these balances on a regular basis and records valuation allowances on the amounts that are not expected to be recovered.

Deferred Offering Costs

Deferred offering costs, consisting of legal, accounting and other third-party fees directly relating to in-process equity financings or offerings are capitalized. Deferred offering costs are offset against offering proceeds upon the completion of the financing or the offering. In the event the financing or the offering is terminated or delayed, deferred offering costs are expensed immediately as a charge to general and administrative expenses in the consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, the Company had $0.4 million and zero deferred offering costs, respectively, in other assets, non-current in its consolidated balance sheets.

Property and Equipment, Net

Property and equipment are stated at cost less accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of assets. Costs for capital assets not yet placed into service are capitalized as construction-in-progress and depreciated once placed into service. Repair and maintenance costs that are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred. Improvements are capitalized as additions to property and equipment. Upon sale or retirement of assets, the costs and related accumulated depreciation are removed from the consolidated balance sheets and the resulting gain or loss is reflected within operating expenses in the consolidated statements of operations and comprehensive loss.

Asset Acquisitions and Acquired IPR&D Assets

The Company measures and recognizes asset acquisitions that are not deemed to be business combinations based on the

cost to acquire the asset or group of assets, which includes transaction costs. The Company determines if the acquisition should be accounted for as an asset acquisition after considering whether substantially all of the fair value of the gross assets acquired is concentrated in a single asset or group of assets and whether the Company acquired a substantive process capable of significantly contributing to the Company's ability to create outputs. Goodwill is not recognized in asset acquisitions. If acquired in-process technology assets, including licenses, know-how and patents are determined to not have an alternative future use, the cost is charged to research and development expenses at the acquisition date.

The Company accounts for contingent consideration identified in an asset acquisition that does not meet the definition of a derivative under ASC 815, *Derivatives and Hedging*, when the payment becomes probable and reasonably estimable. Such amounts are expensed or capitalized based on the nature of the associated asset at the date the related contingency is recognized.

Leases

The Company determines whether an arrangement is or contains a lease at the inception of the arrangement and whether such a lease should be classified as a financing lease or operating lease at the commencement date of the lease. Leases with a term greater than one year are classified as operating lease right-of-use assets, net and operating lease liabilities, current and non-current in the consolidated balance sheets. The Company elected not to recognize the right-of-use assets and lease liabilities for leases with lease terms of one year or less (short-term leases). Lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the lease term. The Company considers the lease term to be the noncancelable period that it has the right to use the underlying asset, together with any periods where it is reasonably certain it will exercise an option to extend (or not terminate) the lease. As the interest rate implicit in the Company's lease contracts is not readily determinable, the Company utilizes its incremental borrowing rate to determine the present value of lease payments. The incremental borrowing rate is derived from information available at the lease commencement date and represents the rate of interest that a lessee would have to pay to borrow an amount equal to the lease payments on a collateralized basis over a similar term in a similar economic environment.

Rent expense for operating leases is recognized on a straight-line basis over the lease term. The Company has elected to not separate lease and non-lease components for its real estate leases and instead accounts for each separate lease component and the non-lease components associated with that lease component as a single lease component. Variable lease payments are recognized as incurred.

As of December 31, 2025 and 2024, the Company had no finance leases.

Impairment of Definite-Lived Long-Lived Assets

The Company regularly reviews the carrying value and estimated lives of all of its definite-lived long-lived assets, including property and equipment, and right-of-use assets to determine whether indicators of impairment may exist that warrant adjustments to carrying values or estimated useful lives. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset group to future undiscounted net cash flows expected to be generated by the asset or asset group. Should impairment exist, the impairment loss to be recognized is measured by the amount by which the carrying amount of the asset exceeds the projected discounted future net cash flows arising from the asset.

Derivative Liability

The Company may issue financial instruments, such as promissory notes, that include embedded derivatives, such as call options. Derivatives are accounted for under ASC 815, *Derivatives and Hedging*. The Company performs analysis of derivatives embedded in the financial instruments, and if any require bifurcation, accounts for these at fair value at the issuance date. A derivative liability is accounted for separately from the financial instrument at fair value on the issuance date and is remeasured each reporting period. The changes in the fair value of the derivative liability are included in change in fair value of derivative liability in the consolidated statements of operations and comprehensive loss.

In March 2024, in connection with the Company's redeemable convertible preferred stock financings, the Company issued options to purchase additional shares of redeemable convertible preferred stock at a specified price, which were accounted for as derivative liabilities. Changes in fair value of these derivative liabilities were included in the other income (loss) in the consolidated statement of operations and comprehensive loss for each reporting period until the derivatives were settled in May 2024 (see Note 4).

Redeemable Convertible Preferred Stock

The Company recorded redeemable convertible preferred stock at their respective fair values on the dates of issuance, net of offering costs. The redeemable convertible preferred stock was recorded outside of permanent equity because while it was not mandatory, redemption was contingent upon the occurrence of certain events considered not solely within the Company's control. The Company did not adjust the carrying values of the redeemable convertible preferred stock to the liquidation preferences of such stock, because it was uncertain whether or when a deemed liquidation event would occur that would obligate the Company to pay the liquidation preferences to holders of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences would be made only when it became probable that such a deemed liquidation event would occur. All redeemable convertible preferred stock outstanding was converted into common stock immediately prior to the closing of the IPO on July 1, 2024, and the Company had no outstanding redeemable convertible preferred stock outstanding as of December 31, 2025 and 2024.

Research and Development Expenses and Accruals

Research and development costs are expensed as incurred. Research and development costs consist primarily of costs associated with acquiring technology and intellectual property licenses that have no alternative future uses, costs incurred under in-license or assignment agreements, salaries and benefits of research and development personnel, costs related to research activities, preclinical studies, clinical trials, drug manufacturing, third-party professional research and development consulting services, and allocated overhead and facility-related expenses. Payments associated with licensing agreements to acquire exclusive licenses to develop, use, manufacture and commercialize products that have not reached technological feasibility and do not have alternate future use will also be expensed as incurred.

The Company records accrued liabilities for estimated costs of its research and development activities conducted by third-party service providers. The Company accrues these costs based on factors such as estimates of the work completed and in accordance with the third-party service agreements. If the Company does not identify costs that have begun to be incurred or if the Company underestimates or overestimates the level of services performed or the costs of these services, actual expenses could differ from the estimates. To date, the Company has not experienced any material differences between accrued costs and actual costs incurred.

Nonrefundable advance payments for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed and classified as current or non-current prepaid expenses and other assets.

The Company makes payments in connection with clinical trials to CMOs that manufacture the materials for its product candidates and to CROs and clinical trial sites that conduct and manage the Company's clinical trials. The financial terms of these contracts are subject to negotiation, which vary by contract and may result in payments that do not match the periods over which materials or services are provided. Generally, these agreements set forth the scope of work to be performed at a fixed fee, unit price or on a time and materials basis. The Company makes estimates of accrued research and development expenses as of each balance sheet date based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments, if necessary. Research and development accruals are estimated based on the level of services performed, progress of the studies, including the phase or completion of events, and contracted costs. The estimated costs of research and development services provided, but not yet invoiced, are included in accrued expenses in the consolidated balance sheets. If the actual timing of the performance of services or the level of effort varies from the original estimates, the Company will adjust the accrual accordingly.

Comprehensive Loss

Comprehensive loss represents all changes in stockholders' deficit except those resulting from distributions to stockholders. The Company's other comprehensive income (loss) for the years ended December 31, 2025 and 2024 consisted of unrealized gain (loss) on marketable securities, net of taxes.

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 in the consolidated statements of operations and comprehensive loss.

Stock-Based Compensation Expense

The Company accounts for stock-based compensation expense in accordance with ASC 718. The Company grants stock-based awards to employees, directors and non-employee consultants in the form of stock options and RSUs to purchase shares of its common stock. The Company measures stock options granted with service-based vesting based on the fair value of the award on the grant date using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions, including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield. The Company expenses the fair value of its stock-based compensation awards on a straight-line basis over the requisite service period, which is the period in which the related services are received.

The Company has also granted stock options with graded vesting based on market, service and performance conditions. At the grant date, the fair value of these stock options was estimated using a Monte Carlo simulation model, which uses a distribution of potential outcomes over the vesting period. The assumptions utilized in the calculation included the Company's expected common stock price, expected volatility, risk-free rate and expected term. Stock-based compensation expense for these awards is recognized on a straight-line basis over the requisite service period, which is the longer of the explicit service period of the service condition and the derived service period of the market condition, as determined for each separately vesting portion of the awards as if each award was, in substance, multiple awards.

Stock-based compensation expense related to stock purchase rights under the Company's 2024 ESPP is measured based on grant date at fair value using the Black-Scholes option-pricing model. The model requires management to make a number of assumptions, including common stock fair value, expected volatility, expected term, risk-free interest rate and expected dividend yield. Stock-based compensation expense is recognized on a straight-line basis over the offering period

The Company accounts for award forfeitures as they occur and classifies stock-based compensation expense in its consolidated statements of operations and comprehensive loss in the same manner in which the award recipient's salary or services costs are classified.

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 consolidated financial statements or in the Company's tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year 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 of deferred tax assets being realized. It provides a valuation allowance when it is more likely than not that some portion or all of a deferred tax asset will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible.

The Company recognizes the tax benefit from an uncertain tax position if it is more likely than not that the tax position will be sustained upon examination by the tax authorities, based on the merits of the position. The Company's policy is to recognize interest and penalties related to the underpayment of income taxes as a component of income tax expense or benefit. To date, there have been no interest or penalties incurred in relation to unrecognized tax benefits.

Net Loss Per Share Attributable to Common Stockholders

Basic and diluted net loss per share attributable to common stockholders is presented in conformity with the two-class method required for participating securities. As such, net income is attributed to common stockholders and participating securities based on their participation rights. Prior to the IPO, under the two-class method, the net loss attributable to common stockholders was not allocated to the redeemable convertible preferred stock as the holders of the redeemable convertible preferred stock did not have a contractual obligation to share in the Company's losses. Upon the IPO, the Company's redeemable convertible preferred stock converted into either Class A or Class B common stock, and were immediately thereafter redesignated into voting and non-voting common stock, respectively, and therefore are included in the allocation of net loss attributable to common stockholders as they share in the Company's losses. Voting and non-voting common stock participate in the Company's losses equally. Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of shares of common stock and potentially dilutive securities outstanding for the period. Potentially dilutive securities include stock options and RSUs issued and outstanding, early exercised stock options, and unvested restricted common stock. As the Company has reported losses for all periods presented, all potentially dilutive securities are antidilutive and accordingly, basic net loss per share equals diluted net loss per share.

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the FASB or other standard setting bodies and adopted by the Company as of the specified effective date. The Company qualifies as an "emerging growth company" as defined in the JOBS Act, and has elected not to "opt out" of the extended transition related to complying with new or revised accounting standards, which means that when a standard is issued or revised and it has different application dates for public and private companies, the Company will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that the Company either (i) irrevocably elects to "opt out" of such extended transition period or (ii) no longer qualifies as an emerging growth company. The Company may choose to early adopt any new or revised accounting standards whenever such early adoption is permitted for private companies.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"), which requires the disclosure of specific categories in the rate reconciliation and greater disaggregation for income taxes paid. ASU 2023-09 is effective for annual periods beginning after December 15, 2024 for public entities and for fiscal years beginning after December 15, 2025 for all other entities, with early application permitted. ASU 2023-09 should be adopted prospectively with the option to be adopted retrospectively. The Company adopted this standard prospectively effective for the year ended December 31, 2025 and reflected the required annual income tax disclosures in the notes to its consolidated financial statements (see Note 15).

Recently Issued and Not Yet Adopted Accounting Pronouncements

In November 2024, the FASB issued ASU No. 2024-03, *Disaggregation of Income Statement Expenses (Topic 220)* ("ASU 2024-03"), requiring that public business entities disclose additional information about specific expense categories in the notes to financial statements at interim and annual reporting periods. The amendments of ASU 2024-03 are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The requirements of ASU 2024-03 may be applied either prospectively to financial statements issued for reporting periods after the effective date or retrospectively to any or all prior periods presented in the financial statements. The

Company is currently evaluating the impact of adopting ASU 2024-03 on its consolidated financial statements and disclosures.

In December 2025, the FASB issued ASU No. 2025-11, *Interim Reporting (Topic 270): Narrow-Scope Improvements* ("ASU 2025-11"), which clarifies the form and content of interim financial statements, adds a comprehensive list of required interim disclosures, and provides a disclosure principle for condensed interim financial statements. ASU 2025-11 is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted and, on adoption, can be applied either prospectively or retrospectively to any or all periods presented in the financial statements. The Company is currently evaluating the impact of the new standard on the Company's consolidated financial statements and related disclosures.

3. Acquisition

ACELYRIN Merger

The Company completed its acquisition of ACELYRIN on the Closing Date of May 21, 2025 and accounted for the transaction as an acquisition under ASC Topic 805, *Business Combinations*. ACELYRIN was a late-stage biopharma company focused on identifying, acquiring, and accelerating the development and commercialization of transformative medicines. ACELYRIN's portfolio consisted of lonigutamab, a subcutaneously delivered, monoclonal antibody targeting IGF-1R for the potential treatment of Thyroid Eye Disease ("TED"). The ACELYRIN Merger strengthened the Company's balance sheet and its cash position and added the lonigutamab product candidate to the Company's development portfolio as of the Closing Date.

As of the Closing Date, the Company (i) issued 48,653,549 shares of its common stock in exchange for ACELYRIN's issued and outstanding common stock shares and paid cash for fractional shares, (ii) assumed ACELYRIN's stock options with an exercise price of $18.00 or less outstanding and unexercised immediately prior to the Closing Date, which are exercisable into 4,712,186 shares of the Company's common stock, (iii) assumed ACELYRIN's RSUs outstanding and unvested immediately prior to the Closing Date, which were converted into 1,323,905 of the Company's RSUs, and (iv) assumed ACELYRIN's performance RSUs outstanding and unvested immediately prior to the Closing Date, which were converted into 146,963 of the Company's RSUs subject only to a service vesting condition.

Outstanding shares, stock options, RSUs and performance RSUs were exchanged at the exchange ratio of 0.4814 shares of the Company's common stock for each share of ACELYRIN common stock (the "Exchange Ratio"). ACELYRIN's outstanding and unexercised options with exercise prices more than $18.00 were cancelled. Exercise prices for the assumed options were determined as the product of the original exercise prices multiplied by the reciprocal of the Exchange Ratio. Converted ACELYRIN stock options and RSUs continue to vest in accordance with their original terms. Performance RSUs were deemed to have 100% satisfied their performance conditions and will vest in two equal installments on May 15 of calendar years 2026 and 2027, subject to the holder of the converted performance RSUs remaining in service with the Company or any of its subsidiaries on such date.

The purchase price consideration consists of the Company's shares of common stock issued as of the Closing Date and the additional stock-based compensation related to the fair value of replacement awards attributable to pre-combination services, and is calculated as follows (in thousands, except share and per share amounts):

Implied shares of common stock issued to holders of ACELYRIN common stock		48,653,549
Closing price per share of common stock as of Closing Date	$	4.78
Consideration transferred for share exchange	$	232,564
Fair value of replacement awards attributable to pre-combination services	$	5,513
Total purchase price consideration	$	238,077

The ACELYRIN Merger was accounted for as a business combination with the Company being treated as the accounting

acquirer. Net assets acquired were recognized at their fair value as of the Closing Date of the ACELYRIN Merger. The Company recognized ACELYRIN Merger transaction costs of $14.7 million in general and administrative expenses in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2025.

The following table presents the final purchase price allocation of the fair value of the net assets acquired and liabilities assumed as of the Closing Date (in thousands):

Assets Acquired		
Cash and cash equivalents	$	49,155
Restricted cash		367
Marketable securities		333,436
Research and development prepaid expenses		958
Prepaid credit voucher for clinical manufacturing		11,376
Other prepaid expenses and current assets		8,081
Restricted cash, non-current		220
Property and equipment		420
Intangible assets		50,959
Operating lease right-of-use assets		4,349
Other assets, non-current		744
Total assets	**$**	**460,065**
Liabilities Assumed		
Accounts payable	$	(6,518)
Research and development accrued expenses		(3,546)
Other accrued expenses and current liabilities		(5,688)
Operating lease liabilities, current		(1,390)
Operating lease liabilities, non-current		(6,238)
Deferred tax liability		(10,701)
Total liabilities		**(34,081)**
Fair value of net assets	**$**	**425,984**
Purchase consideration		238,077
Gain on bargain purchase	**$**	**187,907**

The acquisition method requires, among other things, that assets acquired and liabilities assumed in a business combination be recognized at their fair values as of the Closing Date. Valuing certain components of the ACELYRIN Merger, primarily the acquired IPR&D intangible asset and a deferred tax liability required the Company to make significant estimates and assumptions. The valuation of assets acquired and liabilities assumed was finalized during the three months ended December 31, 2025, which did not result in any measurement period adjustments.

Intangible assets represent the acquired IPR&D intangible asset related to the acquired lonigutamab product candidate in development as of the Closing Date. The fair value of the acquired IPR&D intangible asset was calculated as $51.0 million using the multi-period excess earnings method, which is equal to the present value of the incremental after-tax cash flows attributable to that intangible asset, using a discount rate of 24.0% based on the best estimate of a market participant's after-tax weighted average cost of capital. Projected future cash flows were based on significant estimates, including estimated revenues, costs and probabilities of achieving technical and regulatory milestones, among other factors. The acquired IPR&D intangible asset is an indefinite-lived intangible asset and is subject to an annual impairment test. The Company performed a quantitative analysis for its annual impairment assessment of the acquired IPR&D intangible asset as of December 31, 2025. The quantitative analysis utilized a discounted cash flow model with assumptions that are considered level 3 inputs and concluded that the acquired IPR&D intangible asset had a fair value in excess of its carrying value as of December 31, 2025, and therefore no impairment was identified.

The Company acquired a prepaid credit voucher for clinical manufacturing issued by one of ACELYRIN’s contract

manufacturers that will be applied towards payments of clinical product manufacturing invoices issued by the vendor. The remaining balance of $11.4 million as of the Closing Date was not adjusted from its carrying amount as its fair value approximated its carrying value as of this date.

The Company acquired two operating leases and a sublease. Refer to Note 9 for additional details. The Company estimated the fair value of lease liabilities as the present value of the remaining lease payments, as if the acquired leases were new leases of the acquirer as of the Closing Date. The Company measured the right-of-use asset at the same amount as the lease liability as adjusted to reflect favorable or unfavorable terms of the lease when compared with market terms. As ACELYRIN entered into a sublease in February 2025, these sublease terms were considered at market terms. As of the Closing Date, the fair value of operating lease liabilities, current, increased by $0.2 million and the fair value of operating lease liabilities, non-current, increased by $0.5 million. As of the Closing Date, the fair value of operating lease right-of-use assets, net, decreased by $0.1 million.

Because the fair value of the identifiable assets acquired and liabilities assumed exceeded the fair value of the purchase consideration transferred, the Company recorded a gain on bargain purchase of $187.9 million as of the Closing Date. Consequently, the Company reassessed the recognition and measurement of identifiable assets acquired and liabilities assumed in accordance with ASC 805-30-25-4 and concluded that all acquired assets and assumed liabilities were recognized and that the valuation procedures and resulting measures were appropriate. Gain on bargain purchase primarily relates to the market value of ACELYRIN's common stock trading below the carrying value of net assets and the Exchange Ratio being fixed at the time the Merger Agreement was signed and not adjusted for subsequent changes in the market price of the Company's common stock. Gain on bargain purchase is recognized as other income in the consolidated statements of operations and comprehensive loss. The Company recognized a deferred tax liability of $10.7 million related to the acquired IPR&D intangible asset as of the Closing Date.

The Company also has additional severance related obligations under the Merger Agreement that are separate from the assets and liabilities acquired. In accordance with the ACELYRIN severance plan, ACELYRIN employees terminated without cause within 12 months of the Closing Date are entitled to receive severance benefits, including acceleration of their outstanding equity awards and extension of their outstanding options exercise periods of up to 12 months post-termination. The Company estimated total cash severance obligation, including related taxes, of $11.9 million, which it expects to pay within 12 months from the Closing Date based on agreed termination dates with employees. Severance obligation is recorded to expense over the remaining employment period for notified employees. The Company recognized $6.5 million as general and administrative expenses and $5.4 million as research and development expenses related to severance expenses for the year ended December 31, 2025. As of December 31, 2025, the severance liability of $0.2 million is classified as other accrued expenses and current liabilities in the consolidated balance sheet. The Company estimated stock-based compensation expense of $13.1 million related to the accelerated vesting and exercise term modification for severed employees, which was recognized in the year ended December 31, 2025. The Company recognized stock-based compensation expense of $9.0 million as general and administrative expenses and $4.1 million as research and development expenses for the year ended December 31, 2025.

Following the Closing Date, the operating results of ACELYRIN have been included in the Company's consolidated financial statements. For the period from May 22, 2025 through December 31, 2025, there was no revenue attributable to ACELYRIN, and operating losses attributable to ACELYRIN for such period were $9.3 million.

The ACELYRIN Merger is intended to be a reorganization under Internal Revenue Code Section 368(a). The Merger Agreement outlines the "plan of reorganization" within the meaning of the regulations issued under Internal Revenue Code Section 368(a) and the ACELYRIN Merger is intended to qualify as a tax-free reorganization for U.S. federal and state income tax purposes.

Unaudited Pro Forma Summary of Operations

The following table shows the unaudited pro forma summary of operations for the years ended December 31, 2025 and 2024, as if the ACELYRIN Merger had closed on January 1, 2024. The pro forma financial information is provided for comparative purposes only and is not necessarily indicative of what actual results would have been had the acquisition occurred as of January 1, 2024, nor does it give effect to synergies or any cost savings, and it is not indicative of what such results would be for any future period:

	Year Ended December 31,	
	2025	2024
Total revenue	$ 24,050	$ —
Net loss	(475,071)	(394,155)

The summary pro forma financial information includes the following adjustments:

- actual ACELYRIN Merger transaction costs of $14.7 million were excluded from the year ended December 31, 2025 pro forma results, and included in the year ended December 31, 2024 pro forma results, as if these costs were incurred during the 2024 period;

- incremental stock-based compensation expense related to the accelerated vesting and exercise term modification of $13.1 million was excluded from the years ended December 31, 2025 pro forma results, and included in the year ended December 31, 2024 pro forma results, as if this expense was incurred during the 2024 period;

- severance cash obligation expense for terminated ACELYRIN employees of $11.9 million was excluded from the year ended December 31, 2025 pro forma results, and included in the year ended December 31, 2024 pro forma results, as if this expense was incurred during the 2024 period; and

- Gain on bargain purchase of $187.9 million was excluded from the year ended December 31, 2025 pro forma results, and included in the year ended December 31, 2024 pro forma results, as if such gain was recognized during the 2024 period.

4. Fair Value Measurements

The Company discloses and recognizes the fair value of its assets and liabilities using a hierarchy that prioritizes the inputs to valuation techniques used to measure fair value. The guidance establishes three levels of the fair value hierarchy as follows:

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

Level 2—Observable inputs other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company’s assessment of the significance of a particular input to the fair value measurement in its entirety requires management to make judgments and consider factors specific to the asset or liability. The Company recognizes transfers into and out of levels within the fair value hierarchy in the period in which the actual event or change in circumstances that caused the transfer occurs.

The Company's financial instruments consist of Level 1, Level 2 and Level 3 financial instruments. Changes in the ability to observe valuation inputs may result in a reclassification of levels of certain securities within the fair value hierarchy.

Level 1 financial instruments are comprised of money market funds and U.S. Treasury obligations. Level 2 financial instruments are comprised of U.S. Treasury obligations, corporate debt obligations, commercial paper, supranational debt obligations and government development bank obligations. Short term marketable securities are considered Level 2 when their fair values are determined using inputs that are observable in the market or can be derived principally from or corroborated by observable market data such as pricing for similar securities, recently executed transactions, cash flow models with yield curves, and benchmark securities. In addition, Level 2 financial instruments are valued using comparisons to like-kind financial instruments and models that use readily observable market data as their basis. Level 3 financial instruments include derivative liabilities issued in March 2024 and settled in May 2024 in connection with the closing of the second tranche of the Series C redeemable convertible preferred stock financing.

The following tables present the Company's fair value hierarchy for financial assets measured at fair value on a recurring basis as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 81,729	$ —	$ —	$ 81,729
U.S. treasuries	3,971	—	—	3,971
Marketable securities				
U.S. Treasury obligations	110,809	37,673	—	148,482
Corporate debt obligations	—	30,743	—	30,743
Commercial paper	—	27,672	—	27,672
Supranational debt obligations	—	7,922	—	7,922
Government development bank obligations	—	4,012	—	4,012
Total assets	$ 196,509	$ 108,022	$ —	$ 304,531

	December 31, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents				
Money market funds	$ 168,847	$ —	$ —	$ 168,847
Marketable securities				
U.S. Treasury obligations	47,137	71,600	—	118,737
Total assets	$ 215,984	$ 71,600	$ —	$ 287,584

In connection with the Series C redeemable convertible preferred stock financing in March 2024, the Company issued to investors two freestanding financial instruments: the Series C second tranche option liability and the put right option liability. The Company estimated their fair value using a Black-Scholes option-pricing model weighted by the probability of occurring. The Company used the intrinsic value calculation to estimate the fair value of the Series C second tranche option liability and the put right option liability upon settlement. Significant estimates and assumptions impacting the derivative liability fair value included the probability of each option exercise, redeemable convertible preferred stock fair value, estimated stock volatility and the expected term.

The following table provides a range of assumptions used in the valuation of the derivative liability for the year ended December 31, 2024:

	Year Ended December 31, 2024
Expected term (in years)	0.2 – 0.4
Volatility	55.1% – 59.9%
Risk-free interest rate	5.4% – 5.5%
Dividend yield	0.00%
Probability of option exercise	0.0% – 100.0%

The following table provides a roll-forward of the fair value of the Company's Level 3 financial instruments, the derivative liability, for the year ended December 31, 2024 (in thousands):

	Year Ended December 31, 2024
Fair value at beginning of period	$ —
Fair value upon issuance	8,913
Changes in fair value	5,406
Fair value upon settlement	(14,319)
Fair value at end of period	$ —

The Company did not hold Level 3 financial instruments for the year ended December 31, 2025. There were no transfers between Level 1, Level 2 or Level 3 categories for the years ended December 31, 2025 and 2024.

5. Marketable Securities

Marketable securities, which are classified as available-for-sale, consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term marketable securities:				
U.S. Treasury obligations	$ 148,352	$ 129	$ —	$ 148,481
Corporate debt obligations	30,720	24	—	30,744
Commercial paper	27,652	20	—	27,672
Supranational debt obligations	7,913	9	—	7,922
Government development bank obligations	4,006	6	—	4,012
Total short-term marketable securities	$ 218,643	$ 188	$ —	$ 218,831

	December 31, 2024			
	Amortized Cost Basis	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Short-term marketable securities:				
U.S. Treasury obligations	$ 118,697	$ 45	$ (5)	$ 118,737
Total short-term marketable securities	$ 118,697	$ 45	$ (5)	$ 118,737

All marketable securities held as of December 31, 2025 and 2024 had contractual maturities of less than one year.

As of December 31, 2025 and 2024, no significant facts or circumstances were present to indicate a deterioration in the creditworthiness of the issuers of the marketable securities, and the Company has no requirement or intention to sell these securities before maturity or recovery of their amortized cost basis. The Company considered the current and expected future economic and market conditions and determined that its marketable securities were not significantly impacted. For all marketable securities with a fair value less than its amortized cost basis, the Company determined the decline in fair value below amortized cost basis to be immaterial and non-credit related, and therefore no allowance for expected credit losses was recorded for the years ended December 31, 2025 and 2024.

6. Balance Sheet Components

Restricted cash

Restricted cash includes cash held at financial institutions that is pledged as collateral for stand-by letters of credit of $1.3 million and $1.1 million related to lease commitments as of December 31, 2025 and 2024, respectively. The cash will be restricted until the termination or modification of the related lease agreements. Restricted cash is classified as restricted cash, non-current in the consolidated balance sheets as of December 31, 2025 and 2024.

Other Prepaid Expenses and Current Assets

Other prepaid expenses and current assets consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Prepaid subscriptions	$ 2,088	$ 1,232
Interest receivable	1,343	698
Prepaid insurance	744	695
Tax receivable	740	1,114
Prepaid credit voucher for clinical manufacturing	683	—
Other	1,142	762
Total other prepaid expenses and current assets	$ 6,740	$ 4,501

The prepaid credit voucher for clinical manufacturing was received by ACELYRIN in the third quarter of 2024 as part of an agreement to cancel certain services with a vendor under a manufacturing agreement related to the suspension of development of certain ACELYRIN programs. The prepaid credit voucher for clinical manufacturing may be used to settle invoices for services and raw materials from this vendor related to the lonigutamab product candidate. As of December 31, 2025, the prepaid credit voucher for clinical manufacturing included $0.7 million classified in other prepaid expenses and current assets and $5.5 million included in other assets, non-current.

Property and Equipment, net

Property and equipment, net consisted of the following as of December 31, 2025 and 2024 (in thousands):

	Estimated Useful Life (in years)	December 31, 2025	December 31, 2024
Leasehold improvements	Shorter of useful life or lease term	$ 17,655	$ 17,618
Laboratory equipment	5	5,843	5,227
Furniture and fixtures	5	1,709	1,709
Computer equipment	5	896	896
Capitalized software	3	75	75
Total property and equipment, gross		26,178	25,525
Less: Accumulated depreciation and amortization		(7,988)	(4,557)
Total property and equipment, net		$ 18,190	$ 20,968

Depreciation and amortization expense was $3.5 million and $3.2 million for the years ended December 31, 2025 and 2024, respectively.

Other Accrued Expenses and Current Liabilities

Other accrued expenses and current liabilities consisted of the following as of December 31, 2025 and 2024 (in thousands):

	December 31, 2025	December 31, 2024
Accrued personnel and related expenses	$ 17,581	$ 7,765
Accrued professional services and other	4,397	2,657
Severance liability	244	—
Accrued other expenses	81	158
Total other accrued expenses and current liabilities	$ 22,303	$ 10,580

7. Revenue

Kaken Collaboration Agreement

On March 25, 2025, (the "Effective Date") the Company entered into the Kaken Collaboration Agreement. Under the terms of the Collaboration Agreement, the Company granted to Kaken an exclusive right to develop, manufacture and commercialize envu, formerly known as ESK-001, for dermatology indications in Japan, with options to expand the license, subject to opt-in payments and certain cost-sharing obligations on the part of Kaken, to include rheumatological and gastrointestinal diseases.

Pursuant to the terms of the Collaboration Agreement, the Company is responsible for the global development of envu in the dermatology field, and Kaken is responsible for the clinical development, regulatory approvals and commercialization of envu in Japan in dermatology and other indications for which Kaken has exercised its option. Kaken is required to use commercially reasonable efforts to conduct all subsequent development, manufacture, and commercialization activities. The Collaboration Agreement further provides that the Company will retain rights to envu in all other indications and geographies.

In March 2025, Kaken made an upfront, non-refundable payment of $20.0 million to the Company. In addition, Kaken will pay the Company an aggregate of $20.0 million towards global development costs for envu in the dermatology field through the end of 2026 and thereafter will pay a specified share of development costs applicable to the dermatology field, and for any field for which Kaken exercises its option, subject to Kaken's right to opt out of cost-sharing in certain

indications in specified circumstances. In addition, Kaken would pay the Company up to an aggregate of $36.0 million upon the achievement of regulatory milestones and upon Kaken's exercise of its field expansion options for the rheumatology and gastrointestinal fields. In addition, the Company is entitled to receive aggregate payments of up to ¥15.5 billion upon the achievement of commercial milestones, plus tiered royalties at percentages ranging from the low double digits into the twenties on aggregate net sales of envu in Japan.

The Company evaluated the Collaboration Agreement and concluded it was within the scope of ASC 606. As of the Effective Date, the Company identified four performance obligations: (1) license to develop, manufacture and commercialize envu (the "License Obligation"), (2) development services that support the global development of envu (the "Development Services Obligation"), (3) the manufacture of the clinical supply in Japan (the "Manufacturing Services Obligation") and (4) a material right related to the option for rheumatology disease (the "Material Right Obligation"). The License Obligation was considered functional intellectual property and distinct from other promises under the contract, as Kaken can benefit from the license on its own or together with other readily available resources. The Development Services Obligation and Manufacturing Services Obligation were considered distinct as Kaken could benefit from both of these separately with the license transferred by the Company at the inception of the agreement. The option in the rheumatology field contained a material right because its exercise does not require payment of a fee that is commensurate with the value of the additional license. No material right was assigned to the gastrointestinal field since its estimated fair value did not exceed the exercise price of the option.

The transaction price includes the upfront license fee of $20.0 million, the global development cost reimbursement of $20.0 million in the dermatology field through the end of 2026, the estimated global development cost reimbursement in the dermatology field after 2026 of $1.5 million and an immaterial amount of variable consideration related to the Manufacturing Services Obligation. The Company determined that any variable consideration related to development and regulatory milestones was deemed to be fully constrained at inception and therefore excluded from the initial transaction price due to the high degree of uncertainty and risk associated with these potential payments, and the Company could not assert that it was probable that a significant reversal in the amount of cumulative revenue recognized would not occur.

The Company developed the estimated standalone selling prices for the License Obligation and Material Right Obligation primarily based on the probability-weighted value of expected future revenues associated with each underlying license. In developing such estimates, the Company applied judgment in determining the forecasted revenue, taking into consideration the applicable market conditions, the probability of success, and the time needed to develop each indication for which the license relates. The Company developed the estimated standalone selling price for the development services and clinical supply primarily based on the resources to be committed to perform the service.

At inception of the contract, the Company allocated $17.4 million to the License Obligation, $20.8 million to the Development Services Obligation, $3.3 million to the Material Right Obligation and an immaterial amount to the Manufacturing Services Obligation. The License Obligation was satisfied in March 2025 upon transfer of the license to Kaken. For the Development Services Obligation, the Company recognizes revenue over time as Kaken consumes the benefit of such services as they are being performed. The Company measures proportional performance over time for the Development Services Obligation by using an input method based on cost incurred relative to the total estimated cost of the obligation on a quarterly basis. The Company re-evaluates the transaction price as uncertain events are resolved or other changes in circumstances occur as of the end of each reporting period.

The Company recognized revenue of $17.4 million for the year ended December 31, 2025 related to the License Obligation and $6.7 million for the year ended December 31, 2025 related to the Development Services Obligation and Manufacturing Services Obligation. As of December 31, 2025, collaboration revenue receivable was less than $0.1 million, deferred revenue, current was $1.5 million and deferred revenue, non-current was $2.6 million. The aggregate estimated amount of transaction price that was unsatisfied as of December 31, 2025 was $17.6 million, of which, $14.3 million related to the Development Services Obligation that is expected to be recognized through 2028 as the Company performs its services towards the global development of envu in the dermatology field. The remaining $3.3 million estimated amount of transaction price that was unsatisfied as of December 31, 2025 related to the Material Right Obligation and is deferred until the option is exercised or expires.

Tenet Medicines Purchase Agreement

In January 2024, ACELYRIN entered into an asset purchase agreement ("Purchase Agreement") with Tenet Medicines, Inc. ("Tenet"). In consideration for the assets and other rights Tenet received under the Purchase Agreement, ACELYRIN is entitled to receive development, regulatory and commercial milestone payments of up to $157.5 million in the aggregate based on the achievement of specified milestones, royalties on worldwide net sales, and payments on sublicense income. On December 31, 2025, Climb Bio, Inc. ("Climb Bio"), the parent company of Tenet, filed a complaint in Delaware Superior Court seeking a declaratory judgment that budoprutug is not a "Product" under the Purchase Agreement, and therefore Climb Bio does not owe milestone or royalty payments to the Company under the Purchase Agreement. In January 2026, the Company issued a notice of material breach to Climb Bio for failing to timely pay a $3.0 million development milestone. The Company disputes Climb Bio's interpretation and intends to seek recovery of the $3.0 million development milestone, as well as any other future milestone or royalty payments, through litigation. The matter remains pending.

8. Related Party Transactions

Foresite Labs Services Agreement

Foresite Labs, LLC ("Foresite Labs") is an affiliate of Foresite Capital Management, a stockholder of the Company. In January 2021, the Company entered into a services agreement with Foresite Labs, which was amended and restated in August 2021 and in December 2023, and expires in December 2026, unless terminated earlier by the parties. Thereafter, on each anniversary of the effective date, the agreement will automatically renew for an additional one-year term, unless terminated earlier by the parties. Foresite Labs provides services to assist the Company in exploring specified immunology genetic targets. For the years ended December 31, 2025 and 2024, the Company recognized $1.1 million and $0.9 million as research and development expenses under the service agreement, respectively. Accrued expenses under the service agreement were zero as of December 31, 2025 and 2024.

9. Commitments and Contingent Liabilities

Operating Leases

In August 2022, the Company entered into a lease agreement for 55,000 square feet of office and laboratory space in South San Francisco, California, which commenced in January 2023 and has a contractual termination date in August 2033. The lease agreement includes a renewal option allowing the Company to extend this lease for an additional three years at the prevailing rental rate, which the Company was not reasonably certain to exercise.

In December 2024, the Company entered into a lease agreement for approximately 22,000 square feet of additional office space in South San Francisco, California. The lease has a contractual termination date of December 2026, with the right to extend the lease for an additional two years subject to certain conditions. The Company determined that, for accounting purposes, the commencement date of the lease is in January 2025 and the lease term ends in December 2026, as it was not reasonably certain that the lease would be extended. As of the commencement date, future lease payments totaled $1.9 million and the lease liability was calculated to be $1.8 million, which is equal to the present value of the future lease payments, discounted at an incremental borrowing rate of 7.9%.

Upon the closing of the ACELYRIN Merger, the Company became the successor to ACELYRIN's rights under ACELYRIN's lease and sublease agreements. In January 2023, ACELYRIN entered into a lease agreement to rent approximately 10,012 square feet of office space in Southern California. The term of the lease is 65 months with an option to extend it for an additional three years. Monthly rent payments are approximately $30,500, subject to an annual 3.0% increase. In addition to the base rent, the Company is obligated to pay variable costs related to its share of operating expenses and taxes. In December 2025, the Company entered into an agreement to sublease the entirety of its Southern California leased space through August 24, 2028, the remainder of the lease term. The sublease included the operating lease right-of-use asset and certain property, plant and equipment. Sublease income was immaterial for the year ended

December 31, 2025.

In July 2023, ACELYRIN entered into a lease agreement to rent approximately 22,365 square feet of office space in South San Francisco, California. The term of the lease is 60 months with an option to extend it for an additional five years. Monthly base rent payments are approximately $150,000, subject to an annual 3.5% increase. In February 2025, ACELYRIN entered into an agreement to sublease the entirety of its South San Francisco leased space through October 2029, the remainder of the lease term. The sublease included the operating lease right-of-use asset and certain property, plant and equipment. Sublease income was immaterial for the year ended December 31, 2025.

The components of lease costs were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Operating lease costs	$ 4,995	$ 3,469
Variable lease costs	1,312	1,202
Total lease costs	$ 6,307	$ 4,671

Supplemental cash flow information related to the operating leases were as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Cash payments included in the measurement of operating lease liabilities	$ 7,079	$ 5,299

Weighted-average remaining lease term and incremental borrowing rate for the operating leases were as follows:

	December 31, 2025	December 31, 2024
Weighted-average remaining lease term (years)	6.8	8.7
Weighted-average incremental borrowing rate	11.6 %	11.4 %

Future minimum lease payments under non-cancelable leases as of December 31, 2025 were as detailed below (in thousands):

2026	$ 8,486
2027	7,648
2028	7,765
2029	7,205
2030	5,848
Thereafter	16,009
Total undiscounted lease payments	52,961
Less: Imputed interest	(16,047)
Total operating lease liabilities	$ 36,914

FronThera Contingent Consideration

In March 2021, the Company entered into the FronThera Acquisition, and the transaction was accounted for as an asset acquisition. Under the stock purchase agreement, the Company is obligated to pay contingent consideration of up to an aggregate of $120.0 million based on the achievement of specified clinical and approval milestones, including receipt of first commercialization approval in the United States or certain other jurisdictions, of up to an aggregate of $70.0 million payable for clinical milestones, and of up to an aggregate of $50.0 million payable for approval milestones, all related to technology acquired under the agreement. In the year ended December 31, 2022, the Company incurred and made a $37.0 million milestone payment for the first administration of envu to a patient enrolled in a Phase 2 clinical trial of envu, which

was recorded in research and development expenses in the consolidated statements of operations and comprehensive loss. In July 2024, the Company met a milestone in connection with the first administration of envu to a patient enrolled in a Phase 3 clinical trial of envu and made a $23.0 million milestone payment in August 2024, which was recorded in research and development expenses in the consolidated statements of operations and comprehensive loss for the year ended December 31, 2024. No other milestones were achieved or were probable of being achieved as December 31, 2025.

License and Commercialization Agreement with Pierre Fabre

Upon the closing of the ACELYRIN Merger, the Company became the successor to ACELYRIN's rights under the March 25, 2021 license and commercialization agreement with Pierre Fabre Medicament SAS ("Pierre Fabre"), as amended (the "Pierre Fabre Agreement"), through which ACELYRIN received certain exclusive worldwide licenses with the right to sublicense certain patents, know-how and other intellectual property to develop, manufacture, use and commercialize lonigutamab for non-oncology therapeutic indications. The license from Pierre Fabre extends to any product containing lonigutamab (excluding any fragments or derivatives) as its sole active ingredient (each, a "PF Licensed Product"). The Pierre Fabre Agreement prohibits the Company from using the licensed intellectual property in any antibody drug conjugate, multi-specific antibodies or any other derivatives of lonigutamab.

The Company is obligated to (i) make payments of up to $100.5 million upon the achievement of various development and regulatory milestones, (ii) make milestone payments of up to $390.0 million upon the achievement of certain commercial milestones, and (iii) pay tiered royalties in the high single-digit to low-teen percentages to Pierre Fabre on worldwide net sales in a given calendar year. Royalties will be payable for each PF Licensed Product in a given country during a period commencing upon the first commercial sale of such PF Licensed Product in such country and continuing until the latest of (a) 10 years after such first commercial sale, (b) expiration of last-to-expire valid claim in a licensed patent in such country and (c) expiration of regulatory exclusivity for such PF Licensed Product in such country. In the event the Company enters into a sublicense with a third party, the Company must also share with Pierre Fabre a percentage of any revenues from option fees, upfront payments, license maintenance fees, milestone payments or the like generated from the sublicense. Such percentage may be between the high single-digits to the low thirties based on which stage of development of a PF Licensed Product the sublicense relates to.

Unless earlier terminated, the Pierre Fabre Agreement will continue on a PF Licensed Product-by-PF Licensed Product and country-by-country basis until there are no more royalty payments owed to Pierre Fabre on any PF Licensed Product thereunder. Either party may terminate the Pierre Fabre Agreement upon an uncured material breach, or upon the bankruptcy or insolvency of the other party. Pierre Fabre may also terminate the agreement if the Company or any of its affiliates institutes a patent challenge against the licensed patents from Pierre Fabre. The Company may also terminate the Pierre Fabre Agreement with or without cause upon nine months' prior written notice, so long as there is no ongoing clinical trial for any PF Licensed Product.

As of December 31, 2025, no milestones were probable and accrued in the consolidated balance sheets.

Purchase Commitments

The Company enters into various agreements in the ordinary course of business, such as those with suppliers, CROs, CMOs and clinical trial sites. Upon the closing of the ACELYRIN Merger, the Company became the successor to contracts with non-cancellable commitments under ACELYRIN contracts. The total value of non-cancellable purchase commitments under contracts was $1.6 million as of December 31, 2025. This presentation of non-cancellable purchase commitments does not include any estimates of potential reduction of such liabilities related to mitigation obligations of the counterparties in the event of cancellation under the terms of its engagements.

Legal Contingencies

From time to time, the Company has and may become involved in legal proceedings arising in the ordinary course of business, any or all of which could have a material adverse impact on the Company, including its financial position. The

outcomes of legal proceedings are not within the Company's complete control and may not be known for prolonged periods of time. The Company records a liability for such matters when it is probable that future losses will be incurred and that such losses can be reasonably estimated. Significant judgment by the Company is required to determine both probability and the estimated amount. Legal costs related to these matters, including attorney fees, are expensed as incurred and are recorded as general and administrative expenses in the consolidated statements of operations and comprehensive loss.

On November 15, 2023, a purported federal securities class action lawsuit was commenced in the United States District Court for the Central District of California. On February 15, 2024, the Court appointed joint lead plaintiffs and lead counsel. An amended complaint was filed on March 26, 2024 (Boukadoum v. Acelyrin, Inc. et al., No. 2:23-cv-09672-FMO-MAA), naming ACELYRIN and then-current and former executive officers and directors as defendants. The complaint alleges that the defendants violated the Exchange Act and Securities Act by misleading investors about the Phase 2b trial of izokibep in hidradenitis suppurativa. The original complaint was filed following ACELYRIN's announcement of the week 16 results from the Part B portion of such Phase 2b trial. The amended complaint seeks damages and an award of reasonable costs and expenses, including attorneys' fees, expert fees and other costs, as well as such other and further relief as the court may deem just and proper. On May 3, 2024, the defendants filed their motion to dismiss the amended complaint, which was granted by the court, with leave to amend, in January 2026. On February 5, 2026, the plaintiffs filed a second amended complaint, which seeks damages and an award of reasonable costs and expenses, as well as such other and further relief as the court may deem just and proper. On February 19, 2026, the defendants filed their motion to dismiss the second amended complaint, which remains pending.

It is possible that additional suits will be filed, or allegations made by stockholders, with respect to these same or other matters and also naming the Company and/or its officers and directors as defendants. This lawsuit and any other potential lawsuits are subject to inherent uncertainties, and the actual defense and disposition costs will depend upon many unknown factors. The outcome of this lawsuit is necessarily uncertain. The Company could be forced to expend significant resources in the defense against this and any other related lawsuits and the Company may not prevail. The Company currently is not able to estimate the possible loss to the Company from this lawsuit, as this lawsuit is currently at an early stage, and such amounts could be material to the Company's financial statements even if the Company prevails in the defense against this lawsuit. The Company cannot be certain how long it may take to resolve this lawsuit or the possible amount of any damages that the Company may be required to pay. As of December 31, 2025, the Company did not consider any payment to be probable or reasonably estimable and had not accrued for any potential liability relating to this lawsuit.

Guarantees and Indemnifications

In the normal course of business, the Company enters into agreements that contain a variety of representations and provide for general indemnification. Its exposure under these agreements is unknown because it involves claims that may be made against the Company in the future. To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at a request in such capacity. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. As of December 31, 2025 and 2024, the Company did not have any material indemnification claims that were probable or reasonably possible and consequently has not recorded related liabilities.

10. Redeemable Convertible Preferred Stock

In March 2024, the Company issued and sold an aggregate of 41,264,891 shares of Series C redeemable convertible preferred stock for gross proceeds of $129.5 million and incurred $0.4 million of offering costs. The purchase price for Series C redeemable convertible preferred stock was $3.13826 per share. Under the Series C stock purchase agreement, any time prior to the earliest of (i) December 31, 2024, (ii) the execution of a letter of intent for the sale of the Company, or (iii) the closing date of the Company's IPO, at the discretion of the Company's board of directors, the Company was obligated to sell and each Series C purchaser was obligated to purchase additional shares of Series C redeemable convertible preferred stock with the amount equal to the purchaser's aggregate purchase price in the first tranche Series C closing less any previous payments by the purchaser as part of the Put Right (as defined below) exercise. If the purchaser did not purchase its full share in the second tranche closing (the "Second Tranche Series C Closing"), all of its existing

shares of Series C redeemable convertible stock and Series C-1 redeemable convertible preferred stock were convertible into voting common stock at a 10-to-1 basis. Additionally, a purchaser had a right to purchase shares of Series C-1 redeemable convertible preferred stock at a purchase price of $4.00 per share beginning from the earlier of (a) September 4, 2024 or (b) the date of a significant partnering or collaboration agreement and expiring upon the earlier of (a) December 31, 2024, (b) the public filing of a registration statement on Form S-1 for the IPO, (c) the Second Tranche Series C Closing and (d) the execution of a letter of intent for the sale of the Company (the "Put Right"). The Put Right could only be exercised once. The Company determined that the Second Tranche Series C Closing and the Put Right were two freestanding financial instruments and recognized the derivative liabilities at their estimated fair value of $8.9 million at the issuance date.

In May 2024, the Company closed the Second Tranche Series C Closing and issued an additional 41,264,892 shares of Series C redeemable convertible preferred stock at a price of $3.13826 per share. The Company received gross proceeds of $129.5 million and incurred $0.2 million of offering costs. Accordingly, the derivative liabilities were settled, and the Company reclassified the derivative liabilities, remeasured at fair value of $14.3 million, into redeemable convertible preferred stock.

Immediately prior to the closing of the Company's IPO on July 1, 2024, all outstanding shares of the Company's redeemable convertible preferred stock were converted and then redesignated into voting and non-voting common stock and are no longer outstanding.

11. Stockholders' Equity (Deficit)

As of December 31, 2023, the Company was authorized to issue 125,000,000 shares of Class A common stock and 85,960,088 shares of Class B common stock, both with par values of $0.0001 per share.

In June 2024, the Company's board of directors approved the amended and restated certificate of incorporation, which was filed upon the closing of the IPO and which authorized the Company to issue up to 50,000,000 shares of preferred stock, with a par value of $0.0001 per share, and 492,815,092 shares of voting common stock and 7,184,908 shares of non-voting common stock, both with par values of $0.0001 per share.

Immediately prior to the closing of the IPO on July 1, 2024, all of the shares of the Company's redeemable convertible preferred stock then outstanding converted to 28,855,656 shares of Class A common stock and 7,184,908 shares of Class B common stock at a 1-for-4.675 conversion ratio. All outstanding Class A common stock shares and all outstanding Class B common stock shares were redesignated immediately thereafter into the same number of shares of voting common stock and non-voting common stock, respectively.

As of December 31, 2025, there were no shares of preferred stock issued or outstanding, and 99,084,365 and 5,622,408 shares of voting common stock and non-voting common stock, respectively, outstanding.

The holders of voting and non-voting common stock have the same rights except that non-voting common stock does not have voting rights, except as may be required by law. Each holder of non-voting common stock has a right to convert each share of non-voting common stock to one share of voting common stock subject to the following limitations. At any time following the Company's registration of any class of equity securities under the Exchange Act, the holders of shares of non-voting common stock may not convert a number of shares of non-voting common stock into shares of voting common stock in excess of that number of shares of non-voting common stock which would cause the holder thereof to beneficially own (for purposes of Section 13(d) of the Exchange Act), in excess of 4.99% of the total number of issued and outstanding shares of voting common stock. Such maximum percentage may be increased or decreased to such other percentage as any holder of outstanding shares of non-voting common stock may designate in writing (in the case of an increase upon 61 days' prior written notice).

Common stock reserved for issuance, on an as-converted basis, consisted of the following as of December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Stock options issued and outstanding	20,353,098	9,458,788
RSUs issued and outstanding	2,527,377	—
Shares available for grant under the 2024 Equity Incentive Plan	597,112	6,893,517
Shares available for grant under the 2024 Employee Stock Purchase Plan	805,334	650,000
Shares available for grant under the ACELYRIN, Inc. 2023 Equity Incentive Plan	6,585,521	—
Shares available for grant under the 2024 Performance Option Plan	200,208	92,800
Total	31,068,650	17,095,105

Common Stock Issued to Executives

In February 2021, the Company issued 100,532 shares of restricted common stock to two executives at a purchase price of $0.94 per share. The shares vested over a four-year period with a one-year cliff vesting. While the shares were unvested, the holders had voting and dividends rights and the Company had the right to repurchase unvested shares of common stock at the price paid by the holder in the event of termination of the holder's continuous status as a service provider. The Company estimated the fair value of the restricted stock awards based on the fair value of common stock at the grant dates. The expense was recognized ratably over the vesting terms. The Company recognized less than $0.1 million of stock-based compensation expense related to restricted stock awards for each of the years ended December 31, 2025 and 2024.

The following table summarizes the activity for the Company's restricted common stock for the years ended December 31, 2025 and 2024:

	Number of Shares	Weighted-Average Grant Date Fair Value
Unvested as of December 31, 2024	2,583	$ 2.90
Vested	(2,583)	$ 2.90
Unvested as of December 31, 2025	—	$ —

12. Stock-Based Compensation

2021 Stock Plan

In February 2021, the Company adopted the 2021 Stock Plan (the "2021 Plan"), which provided for stock awards to eligible employees, directors and consultants of the Company. Awards issuable under the 2021 Plan included incentive stock options ("ISOs"), non-statutory stock options ("NSOs"), RSUs and stock grants. Subsequent to the adoption of the 2024 Equity Incentive Plan (the "2024 EIP") in June 2024, described below, no additional shares were available for issuance under the 2021 Plan, and any stock options granted under the 2021 Plan that were subsequently forfeited would be made available for issuance under the 2024 EIP.

The terms of the 2021 Plan permit option holders to exercise options before their options are vested. The shares of common stock granted upon early exercise that have not yet vested are subject to repurchase by the Company in the event of termination of the holder's continuous status as a service provider, at the price paid by the holder.

Stock Option Repricing

In March 2024, the Company's board of directors approved the repricing of all outstanding options as of March 29, 2024, which had an exercise price exceeding $8.84 per share. The exercise price of outstanding options with a weighted average

exercise price of $10.23 for 4,603,443 common stock shares was reduced to the estimated common stock fair value of $8.84 per share at the date of the repricing. The vesting terms and expiration dates remain unchanged from the original grant dates.

The stock option repricing was treated as an option modification for accounting purposes and resulted in total incremental expense of $0.7 million, of which $0.1 million incremental expense associated with the vested options was recognized on the modification date. The remaining $0.6 million incremental expense associated with the unvested options as of the modification date is being recognized over the remainder of the original requisite service period.

2024 Performance Option Plan

In May 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 Performance Option Plan (the "2024 POP"). The Company reserved 1,880,680 shares of common stock issuable under the 2024 POP. The 2024 POP permits grants of ISOs, NSOs and restricted stock awards to the Company's employees, directors and consultants.

In May 2024, the Company granted NSOs to employees to purchase 1,880,680 shares of common stock at an exercise price of $10.19 under the 2024 POP. Options generally vest on the date when the Company meets certain common stock public market price specified targets after the end of the IPO lock-up period, subject to continuous service through each respective vest date. The price targets are calculated based on the volume weighted average price per share over 30 consecutive trading dates, in accordance with the grant terms. The unvested awards will expire if it is determined that the vesting conditions have not been met during the applicable six-year performance period. The service condition includes monthly vesting over 36 months from the vesting commencement date and the employee's continuous service with the Company through each such monthly vesting date. The terms of the 2024 POP permit option holders to exercise options before their options are vested, if the market condition has been met.

2024 Equity Incentive Plan

In June 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 EIP, which became effective on June 27, 2024, upon execution of the underwriting agreement related to the Company's IPO. The Company reserved 7,800,000 new shares of common stock for issuance under the 2024 EIP. In addition, up to 6,829,339 shares subject to awards under the 2021 Plan that terminate, expire, or lapse for any reason without the delivery of shares, or are reacquired or withheld (or not issued) to satisfy a tax withholding obligation or the purchase or exercise price, were authorized to be added to the 2024 EIP. The 2024 EIP also provides that the number of shares initially reserved and available for issuance will automatically increase each January 1, beginning on January 1, 2025 through January 1, 2034, by an amount equal to 5% of the outstanding number of shares of the Company's common stock as of the last day of the immediately preceding fiscal year, or such lesser number of shares as determined by the board of directors prior to the applicable January 1. Pursuant to this evergreen provision, the Company increased the number of shares reserved under the 2024 EIP by 2,720,366 on January 1, 2025. No more than 43,888,017 shares of common stock may be issued upon the exercise of incentive stock options under the 2024 EIP.

The 2024 EIP allows the Company to make equity-based awards to its officers, employees, directors and consultants. The 2024 EIP provides for the grant of ISOs, NSOs, restricted stock awards, RSUs, stock appreciation rights, performance awards and other stock-based awards. Options under the 2024 EIP may be granted for periods of up to 10 years at exercise prices no less than the fair market value of common stock on the date of grant; provided, however, that the exercise price of an incentive stock option granted to a 10% stockholder may not be less than 110% of the fair market value of the shares on the date of grant and such option may not be exercisable after the expiration of five years from the date of grant. Stock option grants under the 2024 EIP generally vest over four years. The grant date fair market value of all awards made under the 2024 EIP and all cash compensation paid by the Company to any non-employee director for services as a director in any fiscal year may not exceed $750,000, increased to $1,000,000 in the fiscal year of their initial service as a non-employee director. The terms of the 2024 EIP do not permit option holders to exercise options before their options are vested.

ACELYRIN Plans

Pursuant to the Merger Agreement, the Company assumed certain stock options, RSUs and performance RSUs outstanding under the ACELYRIN, Inc. 2020 Stock Option and Grant Plan, as amended (the "ACELYRIN 2020 Plan"), the ValenzaBio, Inc. Stock Plan (the "ValenzaBio Plan") and the ACELYRIN, Inc. 2023 Equity Incentive Plan (the "ACELYRIN 2023 Plan" and, together with the ACELYRIN 2020 Plan and the ValenzaBio Plan, the "ACELYRIN Plans"). In connection with the closing of the ACELYRIN Merger, the Company also assumed the ACELYRIN 2023 Plan, which, as modified in connection with such assumption, permits equity awards to be issued to the extent permissible under applicable law and Nasdaq listing rules.

Stock options that were outstanding under the ACELYRIN Plans immediately prior to the Closing Date were assumed by the Company and converted into options to purchase the Company's common stock. RSUs that were outstanding and unvested immediately prior to the Closing Date were assumed by the Company and converted into the Company's RSU awards. Performance RSUs outstanding and unvested immediately prior to the Closing Date were converted into the Company's RSU awards subject only to a service vesting condition.

Stock Option Activity

The following table summarizes the Company's stock option activity, excluding under the 2024 POP, for the year ended December 31, 2025 and includes early exercised shares as part of stock options exercised:

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	7,670,908	$ 9.59	8.2	$ 1,777
Stock options assumed in connection with the ACELYRIN Merger	4,712,186	$ 12.99		
Granted	7,465,188	$ 4.77		
Exercised	(57,659)	$ 8.71		$ 138
Forfeited or expired	(1,117,997)	$ 9.11		
Outstanding, vested and expected to vest as of December 31, 2025	18,672,626	$ 8.56	6.7	$ 44,015
Exercisable as of December 31, 2025	10,844,789	$ 10.68	4.9	$ 9,020

Total exercisable shares of 10,844,789 as of December 31, 2025 included 1,975,031 unvested shares that were early exercisable under the 2021 Plan. The total fair value of stock options vested during the years ended December 31, 2025 and 2024 was $27.0 million and $5.8 million, respectively.

The following table summarizes the Company's stock option activity under the 2024 POP for the year ended December 31, 2025.

	Options	Weighted-Average Exercise Price Per Share	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	1,787,880	$ 10.19	9.3	$ —
Granted	—	$ —		
Forfeited or expired	(107,408)	$ 10.19		
Outstanding, vested and expected to vest as of December 31, 2025	1,680,472	$ 10.19	8.3	$ —
Exercisable as of December 31, 2025	—	$ —	—	$ —

Valuation of Stock Options Granted under Non-Performance Plans

The weighted-average grant date fair value of stock options granted for the years ended December 31, 2025 and 2024 was $3.86 and $9.92 per stock option, respectively.

The fair value of stock options granted for the years ended December 31, 2025 and 2024, was estimated using the Black-Scholes option pricing model with the following assumptions:

	Year Ended December 31,	
	2025	2024
Expected term (in years)	5.2 - 6.1	5.8 - 6.1
Volatility	98.84% - 104.32%	103.65% - 109.78%
Risk-free interest rate	3.69% - 4.65%	3.47% - 4.48%
Dividend yield	0.00%	0.00%

Expected Term

The expected term represents the weighted-average period the stock options are expected to remain outstanding and is based on the options' vesting terms and contractual terms as the Company does not have sufficient historical information to develop reasonable expectations about future exercise patterns and post-vesting employment termination behavior.

Expected Volatility

The expected stock price volatility assumption was determined by examining the historical volatilities for industry peers, as the Company did not have sufficient trading history of its common stock. The Company will continue to use industry peers in determining historical stock price volatility until sufficient historical data of its common stock becomes available.

Risk-Free Interest Rate

The risk-free interest rate assumption is based on the U.S. Treasury instruments whose term was consistent with the expected term of the Company's stock options.

Dividends

The Company has not paid any cash dividends on common stock since inception and does not anticipate paying any dividends in the foreseeable future. Consequently, an expected dividend yield of zero was used.

Valuation of Stock Options Granted under the 2024 POP

Stock options granted under the 2024 POP vest based on service, market and performance conditions (the occurrence of the IPO or a change of control) and are classified as equity financial instruments. At the grant date, the fair value of stock options granted under the 2024 POP was estimated using a Monte Carlo simulation model, which uses a distribution of potential outcomes on a monthly basis over the vesting period prioritizing the most reliable information available. The assumptions utilized in the calculation were based on the achievement of certain stock price thresholds, including the Company's expected common stock price, expected volatility, risk-free rate and expected term. The Company used the following assumptions to estimate the fair value at the grant date in May 2024: common stock fair value of $12.06, vesting term of 6.0 years, volatility of 122.00%, and risk-free rate of 4.38%. The estimates of fair value are uncertain and changes in any of the estimated inputs could have resulted in significant adjustments to the fair value.

The Company's estimated fair value of stock options issued under the 2024 POP of $18.0 million is recognized using graded vesting from July 1, 2024, the closing of the IPO, when the performance condition was met, over the longer of (i) the explicit service period of the service condition of 36 months or (ii) the derived service period between 1.4 years to 2.1 years, as determined for each graded vesting tranche.

Early Exercise of Employee Stock Options

Proceeds from the early exercise of stock options are recorded as share repurchase liability, and as shares vest are recognized to additional paid-in capital in the consolidated balance sheets. As of December 31, 2025 and 2024, there was $0.1 million and $0.8 million share repurchase liability related to unvested shares, respectively, classified as share repurchase liability in the consolidated balance sheets.

The following table summarizes the activity for the Company's early exercised shares for the years ended December 31, 2025 and 2024:

	Number of Shares	Weighted-Average Exercise Price Per Share
Unvested as of December 31, 2023	327,100	$ 5.33
Early exercised	25,034	$ 8.84
Vested	(205,451)	$ 5.62
Unvested as of December 31, 2024	146,683	$ 5.53
Early exercised	—	$ —
Vested	(133,002)	$ 5.17
Unvested as of December 31, 2025	13,681	$ 9.01

2024 Employee Stock Purchase Plan

In June 2024, the Company's board of directors adopted, and its stockholders approved, the 2024 ESPP, which became effective on June 28, 2024, upon execution of the underwriting agreement related to the Company's IPO. The Company initially reserved 650,000 shares of common stock for issuance under the 2024 ESPP. The number of shares of common stock reserved for issuance under the 2024 ESPP will be automatically increased each year for ten calendar years beginning on January 1, 2025 through January 1, 2034, by the lesser of (i) 1% of the total number of shares of our common stock outstanding on the last day of the calendar month before the date of the automatic increase, and (ii) 1,950,000 shares; provided that before the date of any such increase, the board of directors may determine that such increase will be less than the amount in (i) and (ii) above. Pursuant to this evergreen provision, the Company increased the number of shares reserved under the 2024 ESPP by 544,073 on January 1, 2025. The 2024 ESPP allows an eligible employee to purchase shares of common stock at an amount equal to 85% of the lower of the fair market value of the Company's common stock at the beginning of the offering period or at each applicable purchase date during an offering period as established by the

board of directors. The first purchase period commenced on January 24, 2025 and ended on May 20, 2025. During the year ended December 31, 2025, 388,739 shares of common stock were purchased under the 2024 ESPP.

The following table summarizes the Black-Scholes option pricing model used in estimating the fair value of the stock purchase rights under the 2024 ESPP for the year ended December 31, 2025:

	Year Ended December 31, 2025
Expected term (in years)	0.3 - 0.5
Volatility	67.54% - 133.00%
Risk-free interest rate	3.75% - 4.33%
Dividend yield	0.00%

Restricted Stock Units

A summary of unvested RSU activity for the year ended December 31, 2025 is presented in the following table:

	Number of Shares	Weighted-Average Grant Date Fair Value Per Share
RSUs assumed in connection with the ACELYRIN Merger	1,470,868	$ 4.78
RSUs granted	2,456,475	$ 3.95
RSUs released	(1,201,282)	$ 4.78
RSUs forfeited	(198,684)	$ 4.24
Unvested as of December 31, 2025	2,527,377	$ 4.01

Stock-Based Compensation Expense

The following table summarizes stock-based compensation expense recognized in the Company's consolidated statements of operations and comprehensive loss for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Research and development	$ 21,305	$ 10,110
General and administrative	22,219	9,347
Total stock-based compensation expense	$ 43,524	$ 19,457

Stock-based compensation expense included $9.0 million as general and administrative expenses and $4.1 million as research and development expenses for the year ended December 31, 2025, related to accelerated vesting and exercise term modification for severed employees in connection with the ACELYRIN Merger.

The following table summarizes the stock-based compensation expense recognized in the Company's consolidated statements of operations and comprehensive loss by award type for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Stock options	$ 35,861	$ 19,399
RSUs	6,678	—
ESPP	979	—
Restricted stock awards	6	58
Total stock-based compensation expense	$ 43,524	$ 19,457

Stock-based compensation expense related to non-employee awards was $0.8 million and $0.3 million for the years ended December 31, 2025 and 2024, respectively. The Company recognized $7.4 million and $5.7 million in stock-based compensation expense related to the 2024 POP for the years ended December 31, 2025 and 2024.

As of December 31, 2025, there was unrecognized stock-based compensation expense of $60.0 million related to unvested stock options and RSUs which the Company expects to recognize over a remaining weighted-average period of 2.58 years.

13. Employee Benefit Plans

The Company sponsors a qualified 401(k) defined contribution plan covering eligible employees. Participants may contribute a portion of their annual compensation limited to a maximum annual amount set by the Internal Revenue Service. There were no employer contributions under this plan for the years ended December 31, 2025 and 2024. In November 2025, the Company's board of directors approved a Company match of 100% of participating employees' deferral contribution up to 3% of eligible compensation and a 50% match of participating employees' deferral contribution from 3% to 5% of eligible compensation, effective from January 1, 2026.

14. Net Loss Per Share Attributable to Common Stockholders

The following table presents the computation of the basic and diluted net loss per share attributable to common stockholders for the years ended December 31, 2025 and 2024 (in thousands, except share and per share amounts):

	Year Ended December 31,	
	2025	2024
Numerator:		
Net loss	$ (243,325)	$ (294,233)
Denominator:		
Weighted-average shares of common stock outstanding	85,096,243	28,579,979
Less: Weighted-average shares of common stock subject to repurchase	(66,619)	(238,113)
Weighted-average shares of common stock outstanding, basic and diluted	85,029,624	28,341,866
Net loss per share attributable to common stockholders, basic and diluted	$ (2.86)	$ (10.38)

The following outstanding potentially dilutive securities were excluded from the computation of diluted net loss per share attributable to common stockholders for the periods presented, because including them would have been anti-dilutive (on an as-converted basis):

	December 31, 2025	December 31, 2024
Stock options issued and outstanding	20,353,098	9,458,788
RSUs issued and outstanding	2,527,377	—
Common stock issuable under the 2024 ESPP	264,360	—
Early exercised stock options and unvested restricted common stock	13,681	149,266
Total	23,158,516	9,608,054

15. Income Taxes

Net loss before provision for income taxes distributed geographically was as follows for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Domestic	$ (251,886)	$ (294,233)
Foreign	—	—
Total	$ (251,886)	$ (294,233)

The provision for income taxes was as follows for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Current		
Federal	$ —	$ —
State and local	—	—
Foreign	—	—
Total Current	$ —	$ —
Deferred		
Federal	$ (8,561)	$ —
State and local	—	—
Foreign	—	—
Total Deferred	$ (8,561)	$ —
Total income tax provision (benefit)	$ (8,561)	$ —

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

	Year Ended December 31, 2025	
	$	%
Net loss before income taxes	$ (251,886)	
U.S. federal statutory tax rate	(52,896)	21.0 %
State and local income taxes, net of federal effect[(1)]	(3)	- %
Tax credits		
Research and development credits	11,129	(4.4)%
Changes in valuation allowance	64,966	(25.8)%
Nontaxable or nondeductible items		
Nondeductible officer's compensation	593	(0.2)%
Gain on bargain purchase	(39,461)	15.7 %
Stock-based compensation	4,621	(1.9)%
Transaction costs	2,346	(0.9)%
Other	144	(0.1)%
Total	$ (8,561)	3.4 %

(1) The state and local tax effect in this category is not material to the consolidated financial statements.

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to net loss before income taxes for the year ended December 31 2024, prior to the adoption of ASU 2023-09, is as follows (in thousands):

	Year Ended December 31, 2024
Amount at statutory tax rates	$ (61,789)
Permanent differences	3,000
Valuation allowance	64,923
Stock-based compensation	3,356
Federal research and development credit	(9,520)
Other	30
Total	$ —

The Company recognized a benefit from income taxes of $8.6 million for the year ended December 31, 2025. The income tax benefit is primarily related to the realization of deferred tax assets and valuation allowance release as a result of the ACELYRIN Merger. No provision for income taxes was recorded for the year ended December 31, 2024, as the Company operated with taxable losses. The Company has only incurred net operating losses in the United States since inception.

On July 4, 2025, the One Big Beautiful Bill Act (the “OBBBA”) was enacted in the United States. The OBBBA includes significant provisions, including, but not limited to, modifications of capitalization of research and development expenses and accelerated fixed asset depreciation. The adoption of the OBBBA did not have a material impact on the Company’s consolidated financial statements for the year ended December 31, 2025.

Significant components of the deferred tax assets (liabilities) balances as of December 31, 2025 and 2024 were as follows (in thousands):

	December 31, 2025	December 31, 2024
Deferred tax assets:		
Net operating losses	$ 59,420	$ 21,573
Tax credits	8,025	17,407
Research and development capitalization	191,356	74,211
Fixed assets and intangibles	6,898	—
Accruals and reserves	2,002	115
Stock-based compensation	7,559	3,088
Operating lease liabilities	7,754	6,452
Other capitalized expenses	14,160	11,832
Gross deferred tax assets	297,174	134,678
Valuation allowance	(292,978)	(127,990)
Deferred tax assets, net of valuation allowance	$ 4,196	$ 6,688
Deferred tax liabilities:		
Fixed assets and intangibles	$ —	$ (885)
Operating lease right-of-use assets	(6,336)	(5,803)
Deferred tax liabilities	(6,336)	(6,688)
Total net deferred tax assets	$ (2,140)	$ —

A valuation allowance is required to be established when it is more likely than not that all or a portion of a deferred tax asset will not be realized. Realization of deferred tax assets is dependent upon future earnings, the timing and amount of which are uncertain. The Company believes that, based on a number of factors such as the history of operating losses, it is more likely than not that the deferred tax assets will not be fully realized, such that a valuation allowance has been recorded. The valuation allowance increased by $165.0 million and by $66.6 million for the years ended December 31, 2025 and 2024, respectively, primarily due to capitalized research and development expenditures and net operating losses carryforwards.

The following table presents the Company's U.S. federal and state net operating loss carryforwards and tax credits as of December 31, 2025 (in thousands):

	Amount	Begin to Expire
Net operating losses, U.S. federal	$ 264,643	Do not expire
Net operating losses, U.S. federal	$ 16,520	2037
Net operating losses, U.S. states	$ 5,866	2041
Tax credits, U.S. federal	$ 3,493	2045
Tax credits, U.S. states	$ 8,238	2037

Utilization of some of the U.S. federal and state net operating loss and credit carryforwards may be subject to annual limitations due to the change in ownership provisions of the Internal Revenue Code and similar state provisions. The annual limitation may result in the expiration of net operating losses and credits before utilization. As of December 31, 2025, the Company has completed an Internal Revenue Code Section 382 analysis which resulted in the expiration of U.S. federal net credits before utilization and, as such, has recognized a reduction of deferred tax assets. As the Company has recognized a valuation allowance, any potential limitation is not expected to have a material impact to the consolidated financial statements.

Uncertain Tax Positions

A reconciliation of the beginning and ending balances of the unrecognized tax benefits for the years ended December 31, 2025 and 2024, is as follows (in thousands):

	Year Ended December 31,	
	2025	2024
Beginning balance	$ 2,797	$ 4,116
Increases in tax positions in the current period	1,164	1,336
Decreases related to prior year's tax position	(1,985)	(2,655)
Ending balance	$ 1,976	$ 2,797

The entire amount of the unrecognized tax benefits would not impact the Company's effective tax rate if recognized. The Company has elected to include interest and penalties as a component of other income (expense), net. For the years ended December 31, 2025 and 2024, the Company did not recognize any accrued interest and penalties related to unrecognized tax benefits.

As of December 31, 2025, the Company is not under audit by the Internal Revenue Service or any state authority for income taxes for any open years. Due to the Company's net operating loss carryforwards, the Company's domestic income tax returns are open to examination by the Internal Revenue Service beginning with tax year 2017 and by state taxing authorities beginning with tax year 2021.

Income Taxes Paid Disclosure (under ASU 2023-09)

The amounts of cash income taxes paid by the Company for the years ended December 31, 2025 and 2024 were immaterial.

16. Segment Reporting

For purposes of evaluating performance and allocating resources, the Company's CODM, its Chief Executive Officer, regularly reviews consolidated net loss as reported in the Company's consolidated statements of operations and comprehensive loss as compared to budget. The measure of segment assets is reported in the consolidated balance sheets as total consolidated assets.

In addition to the significant expense categories included within consolidated net loss presented in the Company's consolidated statements of operations and comprehensive loss, see below for disaggregated amounts that comprise research and development expenses for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Revenue:		
License revenue	$ 17,389	$ —
Collaboration revenue	6,661	—
Total revenue	24,050	—
Operating expenses:		
Research and development expenses		
External costs		
Milestones related to previously acquired IPR&D assets	—	23,000
CROs, CMOs and clinical trials	231,118	151,422
Professional consulting services	30,157	19,154
Other research and development costs	9,096	10,258
Internal costs		
Personnel-related costs	92,702	46,774
Facilities and overhead costs	22,925	14,946
Total research and development expense	385,998	265,554
General and administrative expenses	91,856	35,200
Total operating expenses	477,854	300,754
Loss from operations	(453,804)	(300,754)
Total other income (expense), net	201,918	6,521
Net loss before income taxes	(251,886)	(294,233)
Income tax benefit	8,561	—
Net loss	$ (243,325)	$ (294,233)

17. Subsequent Events

On March 18, 2026, the Company entered into a Controlled Equity Offering℠ Sales Agreement (the "Sales Agreement") with Cantor as sales agent, pursuant to which the Company may offer and sell, from time to time through Cantor, at its option, shares of its common stock having an aggregate offering price of up to $300.0 million (the "ATM Shares"). The sales of the ATM Shares will be made by any method permitted that is deemed to be an "at-the-market" equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq Global Select Market. The Company agreed to pay Cantor a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold by Cantor.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of the Effectiveness of Disclosure Controls and Procedures

As of December 31, 2025, management, with the participation and supervision of our Chief Executive Officer and our Chief Financial Officer, have evaluated our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act. Based on that evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that, as of December 31, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that information we are required to disclose in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure.

Management's Annual Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act as a process designed by, or under the supervision of, a company's principal executive officer and principal financial officer, or persons performing similar functions, and effected by a company's board of directors, management, and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of a company's assets;

- provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that a company's receipts and expenditures are being made only in accordance with authorizations of the company's management and directors; and

- provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

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

Under the supervision of and with the participation of our principal executive officer and principal financial officer, our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025 based on the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control — Integrated Framework (2013 framework). Based on this assessment, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Management excluded certain elements of internal control over financial reporting of ACELYRIN from its assessment of the Company's internal control over financial reporting as of December 31, 2025, because ACELYRIN was acquired by the Company in a purchase business combination during 2025. Subsequent to the acquisition, certain elements of ACELYRIN's internal control over financial reporting and related processes were integrated into the Company's existing systems and internal control over financial reporting. Those controls that were not integrated have been excluded from management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2025. The

excluded elements represent controls over approximately 5% of consolidated total assets, 10% of consolidated total liabilities, 0% of consolidated total revenue and 2% of consolidated total operating expenses.

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm due to our status as an emerging growth company under the JOBS Act.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

Trading Arrangements

During the fourth quarter of 2025, neither the Company nor any of its director or officers adopted or terminated any 10b5-1 trading plan intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) or any other non-Rule 10b5-1 trading arrangement.

"At the Market" Equity Offering Program

On March 18, 2026, we entered into the Sales Agreement with Cantor as sales agent, pursuant to which we may offer and sell, from time to time through Cantor, at our option, shares of our common stock having an aggregate offering price of up to $300.0 million.

The sales of the ATM Shares will be made by any method permitted that is deemed to be an "at-the-market" equity offering as defined in Rule 415(a)(4) promulgated under the Securities Act, including sales made directly on or through the Nasdaq Global Select Market. We agreed to pay Cantor a commission of up to 3.0% of the aggregate gross proceeds from any ATM Shares sold by Cantor.

The foregoing description of the Sales Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Sales Agreement, a copy of which is filed as Exhibit 10.24 to this Annual Report on Form 10-K.

The foregoing disclosure shall not constitute an offer to sell or the solicitation of an offer to buy the securities discussed herein, nor shall there be any offer, solicitation, or sale of the securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Our Board of Directors

Our business affairs are managed under the direction of our board of directors (the "Board"), which currently consists of seven members. Six of our directors are independent within the meaning of the listing standards of The Nasdaq Stock Market ("Nasdaq"). Our Board is divided into three classes. Each class consists, as nearly as possible, of one-third of the total number of directors, and each class has a three-year term, the terms of office of the respective classes expiring in successive years. Vacancies on the Board may only be filled by the affirmative vote of a majority of the remaining directors then in office, and not by our stockholders. A director elected by the Board to fill a vacancy in a class, including vacancies created by an increase in the number of directors, shall serve for the remainder of the full term of that class and until the director's successor is duly elected and qualified or such director's earlier death, resignation or removal. At each annual meeting of stockholders, a class of directors will be elected for a three-year term to succeed the same class whose term is then expiring.

The following is a brief biography of each member of the Board, including their respective ages as of March 19, 2026.

Class I Directors Continuing in Office Until the 2028 Annual Meeting of Stockholders

Srinivas Akkaraju, M.D., Ph.D., age 57, has served as a member of the Board since March 2024. Dr. Akkaraju is a founder and managing member of Samsara BioCapital, a venture capital firm, a position he has held since March 2017, and has been a co-founder and director of Kalaris Therapeutics since August 2025. From April 2013 to February 2016, Dr. Akkaraju served as a general partner of Sofinnova Ventures, a venture capital firm. From January 2009 to April 2013, Dr. Akkaraju served as managing director of New Leaf Venture Partners, a venture capital firm. Dr. Akkaraju presently serves on the board of directors of vTv Therapeutics Inc., Scholar Rock Holding Corporation, Mineralys Therapeutics, Inc., Inventiva S.A., and numerous private biopharmaceutical companies. During the past five years, he served as a director of Syros Pharmaceuticals, Inc., Chinook Therapeutics, Inc., Jiya Acquisition Corp., and Intercept Pharmaceuticals, Inc. Dr. Akkaraju received an M.D. and a Ph.D. in Immunology from Stanford University and undergraduate degrees in Biochemistry and Computer Science from Rice University. We believe that Dr. Akkaraju's extensive investment experience in the biopharmaceutical industry, as well as his scientific background and experience on numerous public and private company boards of directors make him well qualified to serve as a member of the Board.

Sapna Srivastava, Ph.D., age 55, has served as a member of the Board since August 2022. From March 2021 to October 2021, Dr. Srivastava served as the interim Chief Financial Officer at eGenesis, Inc., a biopharmaceutical company. From September 2017 to January 2019, Dr. Srivastava served as the Chief Financial and Strategy Officer at Abide Therapeutics, Inc., a biopharmaceutical company acquired by H. Lundbeck A/S in 2019. From April 2015 to December 2016, Dr. Srivastava served as the Chief Financial and Strategy Officer at Intellia Therapeutics, Inc., a gene editing company. Previously, for nearly 15 years, Dr. Srivastava was a senior biotechnology analyst at Goldman Sachs, Morgan Stanley, and ThinkEquity Partners, LLC. Dr. Srivastava began her career as a research associate at JP Morgan. Dr. Srivastava currently serves on the board of directors of the following public biopharmaceutical companies: Aura Biosciences, Inc. and Nuvalent, Inc. Dr. Srivastava holds a Ph.D. from New York University School of Medicine and a B.Sc. from St. Xavier's College, University of Bombay. We believe that Dr. Srivastava's experience in the pharmaceutical industry makes her well qualified to serve as a member of the Board.

Class II Directors Continuing in Office Until the 2026 Annual Meeting of Stockholders

James B. Tananbaum, M.D., age 62, has served as a member of the Board since May 2021. Dr. Tananbaum is currently the President, Chief Executive Officer and a director of Foresite Capital Management, a U.S.-focused healthcare investment firm, which he founded in 2010. From 2000 to 2010, Dr. Tananbaum served as Co-Founder and Managing Director of Prospect Venture Partners L.P. II and III, healthcare venture partnerships. Dr. Tananbaum was also the Founder of GelTex, Inc. in 1991, an intestinal medicine pharmaceutical company acquired by Sanofi-Genzyme, and Theravance, Inc. in 1997 (now Theravance Biopharma, Inc., a diversified biopharmaceutical company focused on organ-

selective medicines, and Innoviva, Inc., a respiratory-focused healthcare asset management company partnered with Glaxo Group Limited). Dr. Tananbaum presently serves on the board of directors of Eikon Therapeutics, Inc., among other companies. During the past five years, Dr. Tananbaum served on the boards of directors of Fabric Genomics, Inc., Quantum-SI Incorporate, Gemini Therapeutics, Inc., and Kinnate Biopharma Inc., among other companies. Dr. Tananbaum received an M.D. and an M.B.A. from Harvard University, and a B.S. and a B.S.E.E. from Yale University in Applied Math and Computer Science. We believe Dr. Tananbaum's significant executive leadership experience and experience in the healthcare industry make him well qualified to serve as a member of the Board.

Lynn Tetrault, J.D., age 63, has served as a member of our Board since May 2025. Ms. Tetrault currently serves as the Chair of the board of directors of NeoGenomics, Inc., and has been a member of its board of directors since June 2015. Ms. Tetrault has also served as a member of the board of directors of Rhythm Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, since December 2020, and previously served as a member of the board of directors of ACELYRIN, Inc. from December 2023 until May 2025. Previously, Ms. Tetrault served in a variety of executive roles at AstraZeneca PLC from 1993 to 2014 including most recently as Executive Vice President of Human Resources and Corporate Affairs from 2007 to 2014. Ms. Tetrault has a B.A. from Princeton University and a J.D. from the University of Virginia Law School. We believe Ms. Tetrault's decades of experience in the pharmaceutical industry makes her well qualified to serve as a member of our Board.

Zhengbin (Bing) Yao, Ph.D., age 60, has served as a member of the Board since June 2021. From May 2021 to the present, Dr. Yao served as the Chief Executive Officer and chairman of the board of directors of ArriVent Biopharma, a biotechnology company. From March 2018 to March 2021, Dr. Yao served as the Chief Executive Officer, President, and from January 2019 to March 2021 also as chairman of the board of directors of Viela Bio, Inc., a biotechnology company, until it was acquired by Horizon Therapeutics in March 2021. From October 2010 to February 2018, Dr. Yao served as Senior Vice President, Head of Respiratory, Inflammation, Autoimmune iMED at MedImmune, the biologics division of AstraZeneca plc and from October 2015 to February 2018 also as Senior Vice President, Head of Immuno-Oncology Franchise. From March 2008 to September 2010, Dr. Yao served as Head of PTL for Immunology, Infectious Diseases, Neuroscience, and Metabolic Disease at Genentech, Inc., a biopharmaceutical company. From October 2000 to September 2007, Dr. Yao held various leadership roles at Tanox Inc., a biopharmaceutical company, and was Vice President and Head of Research before it was acquired by Genentech, Inc. in 2007. Dr. Yao currently serves on the board of directors of Visen Pharmaceuticals, a biopharmaceutical company, and Nikang Therapeutics, Inc., a biotechnology company. Dr. Yao received his Ph.D. in Microbiology and Immunology from the University of Iowa and M.S. in Immunology from Anhui Medical University in Anhui, China. We believe Dr. Yao's significant experience in the biopharmaceutical industry, particularly in autoimmune disease, and his experience serving as a chief executive officer of a publicly traded biotechnology company make him well qualified to serve as a member of the Board.

Class III Directors Continuing in Office Until the 2027 Annual Meeting of Stockholders

Martin Babler, age 61, has served as our President, Chief Executive Officer, and Chairman of the Board since September 2021. From April 2011 until October 2020, he served as President and Chief Executive Officer at Principia Biopharma Inc., a biotechnology company acquired by Sanofi S.A. From December 2007 to April 2011, Mr. Babler served as President and Chief Executive Officer of Talima Therapeutics, Inc., a pharmaceutical company. From 1998 to 2007, Mr. Babler held several positions at Genentech, Inc., a biopharmaceutical company, most notably as Vice President, Immunology Sales and Marketing. Mr. Babler presently serves on the board of directors of Prelude Therapeutics Inc. and the non-profit organization Biotechnology Innovation Organization, and previously served on the board of directors of 89bio Inc., Sardona Therapeutics, Inc., Neoleukin Therapeutics, Inc., and Omega Alpha SPAC. Mr. Babler received a Swiss Federal Diploma in pharmacy from the Federal Institute of Technology in Zurich and completed the Executive Development Program at the Kellogg Graduate School of Management at Northwestern University. We believe that Mr. Babler's industry and leadership roles, and his knowledge of Alumis as Chief Executive Officer, makes him well qualified to serve on the Board.

Alan B. Colowick, M.D., M.P.H., age 63, has served as a member of the Board since January 2022. Since April 2021, Dr. Colowick has served as the Senior Managing Director of Matrix Capital Management Company. From May 2017 to January 2021, Dr. Colowick served as a private equity partner at Sofinnova Ventures. From 2010 to 2017, Dr. Colowick held various positions at Celgene Corporation, a pharmaceutical company, including Executive Vice President. From 2008

to 2010, Dr. Colowick was the Chief Executive Officer at Gloucester Pharmaceuticals, Inc., a pharmaceutical company, until its acquisition by Celgene in 2010. From 2006 to 2008, Dr. Colowick was President of Oncology for Geron Corporation, a biotechnology company, and from 2005 to 2006 was Chief Medical Officer of Threshold Pharmaceuticals, a pharmaceutical company. From 1999 to 2005, Dr. Colowick held various positions at Amgen Inc., a biopharmaceutical company. Dr. Colowick currently serves as a member on the board of directors of multiple private companies and previously served as a member on the board of directors of ACELYRIN, Inc. from November 2021 to May 2025. Dr. Colowick completed specialty training in Hematology-Oncology at the Dana Farber Cancer Institute/Brigham and Women's Hospital. Dr. Colowick received a M.D. from Stanford University, a M.P.H from Harvard University, and a B.S. in Molecular Biology from the University of Colorado. We believe that Dr. Colowick's extensive professional experience, as well as financial understanding of the biotechnology industry, provide him with the qualifications and skills to serve as a member of the Board.

Patrick Machado, J.D., age 62, has served as a member of the Board since June 2024. Mr. Machado was a co-founder of Medivation, Inc., a biopharmaceutical company, and served as its chief business officer from December 2009 to April 2014 and as its chief financial officer from December 2004 until his retirement in April 2014. From 1998 to 2001, Mr. Machado worked with ProDuct Health, Inc., a medical device company, as senior vice president, chief financial officer and earlier as general counsel. Upon ProDuct Health Inc.'s acquisition by Cytyc Corporation, a diagnostic and medical device company, he served as a consultant to Cytyc Corporation to assist with transitional matters from 2001 to 2002. Earlier in his career, Mr. Machado worked for Morrison & Foerster LLP, an international law firm, and for the Massachusetts Supreme Judicial Court. Mr. Machado serves as a member of the boards of directors of Arcus Biosciences, Inc. and Xenon Pharmaceuticals, Inc., both of which are publicly traded biopharmaceutical companies. Mr. Machado also chairs the board of directors of Prota Therapeutics, and is a member of the board of directors of Avenzo Therapeutics, both of which are privately held biopharmaceutical companies. Mr. Machado previously served on the board of directors of publicly traded companies, such as Adverum Biotechnologies from March 2017 to December 2025, ACELYRIN, Inc. from April 2021 to May 2025, Chimerix, Inc. from June 2014 to June 2024, Turnstone Biologics Inc. from August 2018 to April 2024, Turning Point Therapeutics, Inc. from May 2019 to September 2022, Endocyte, Inc. from February 2018 to December 2018, Axovant Sciences, Inc. from June 2017 to February 2018, SCYNEXIS, Inc. from September 2015 to June 2019, Medivation, Inc. from April 2014 to September 2016, Inotek Pharmaceuticals Corporation (now Rocket Pharmaceuticals, Inc.) from August 2016 to January 2018, and Principia Biopharma Inc. from June 2019 to September 2020; and on the board of directors of privately held companies such as Roivant Sciences, Ltd. from October 2016 to June 2022, and Therachon AG from January 2019 to July 2019. Mr. Machado received a J.D. from Harvard Law School and a B.A. in German and a B.S. in Economics from Santa Clara University. We believe that Mr. Machado's extensive experience dealing with the operational and financial issues of biopharmaceutical companies provide him with the qualifications and skills to serve on the Board.

Family Relationships

There are no family relationships among any of our current directors and executive officers.

Role of Board in Risk Oversight

One of the key functions of the Board is to oversee our risk management process. The Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various standing committees of the Board that address risks inherent in their respective areas of oversight. In particular, the Board is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for us.

The Board also focuses on emerging risks, as well as risk mitigation strategies. Our Audit Committee has the responsibility to consider and discuss, with management and our independent auditors, the major financial risk exposures and the steps our management should take to monitor and control such exposures, including guidelines and policies to govern the process by which risk assessment and management are undertaken. Our Audit Committee also monitors compliance with legal and regulatory requirements, as well as cyber-security risk, in addition to overseeing our internal control over financial reporting and disclosure controls and procedures. Our Compensation Committee also assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk taking.

Committees of Board of Directors

The Board has established an Audit Committee, a Compensation Committee, a Nominating and Corporate Governance Committee and a Science and Technology Committee. The composition and responsibilities of each of the committees of the Board are described below. Members serve on these committees until their resignation or until otherwise determined by the Board. Each committee has adopted a written charter that satisfies the application rules and regulation of the SEC and the listing requirements and rules of The Nasdaq Stock Market LLC (the "Nasdaq Listing Rules"), which we have posted to our website at www.alumis.com. The Board may establish other committees as it deems necessary or appropriate from time to time.

Name	Audit	Compensation	Nominating and Corporate Governance	Science and Technology
Martin Babler				
Srinivas Akkaraju, M.D., Ph.D[1]	X			X
Alan B. Colowick, M.D., M.P.H.	X	X *		X
Patrick Machado, J.D.[2]	X *		X	
Sapna Srivastava, Ph.D.			X *	
James B. Tananbaum, M.D.		X		X
Lynn Tetrault, J.D.[3]		X		
Zhengbin Yao, Ph.D.[4]			X	X *

* Designates Committee Chairperson.

(1) Dr. Akkaraju was appointed to the Audit Committee effective June 21, 2024.

(2) Mr. Machado was appointed to each of the Audit Committee and Corporate Governance Committee effective June 21, 2024.

(3) Ms. Tetrault was appointed to the Compensation Committee effective June 3, 2025.

(4) Dr. Yao ceased serving on the Compensation Committee and was appointed to the Corporate Governance Committee effective June 3, 2025.

Audit Committee

Our Audit Committee currently consists of Srinivas Akkaraju, Alan Colowick and Patrick Machado, each of whom satisfies the independence requirements under the Nasdaq Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of the Audit Committee is Patrick Machado, who qualifies as an "audit committee financial expert" within the meaning of SEC regulations. Each member of our Audit Committee can read and understand fundamental financial statements in accordance with applicable requirements. In arriving at these determinations, the Board has examined each audit committee member's scope of experience and the nature of their employment in the corporate finance sector.

The primary purpose of the Audit Committee is to discharge the responsibilities of the Board with respect to our corporate accounting and financial reporting processes, systems of internal control and financial-statement audits, and to oversee our independent registered accounting firm. Specific responsibilities of our Audit Committee include:

- helping the Board oversee its corporate accounting and financial reporting processes;
- managing the selection, engagement, qualifications, independence and performance of a qualified firm to serve as the independent registered public accounting firm to audit our financial statements;
- discussing the scope and results of the audit with the independent registered public accounting firm, and reviewing, with management and the independent accountants, our interim and year-end operating results;

- developing procedures for employees to submit concerns anonymously about questionable accounting or audit matters;

- reviewing related person transactions;

- obtaining and reviewing a report by the independent registered public accounting firm at least annually, that describes our internal quality control procedures, any material issues with such procedures, and any steps taken to deal with such issues when required by applicable law; and

- approving, or, as permitted, pre-approving, audit and permissible non-audit services to be performed by the independent registered public accounting firm.

Compensation Committee

Our Compensation Committee consists of Alan Colowick, James Tananbaum and Lynn Tetrault. The chair of the Compensation Committee is Alan Colowick. The Board has determined that each member of our Compensation Committee is independent under the Nasdaq Listing Rules.

The primary purpose of Compensation Committee is to discharge the responsibilities of the Board in overseeing our compensation policies, plans and programs and to review and determine the compensation to be paid to our executive officers and directors. Specific responsibilities of our Compensation Committee include:

- reviewing and approving the compensation of our chief executive officer, other executive officers and senior management;

- reviewing and recommending to the Board the compensation paid to our directors;

- reviewing and approving the compensation arrangements with our executive officers and other senior management;

- administering our equity incentive plans and other benefit programs;

- reviewing, adopting, amending and terminating, incentive compensation and equity plans, severance agreements, profit sharing plans, bonus plans, change-of-control protections and any other compensatory arrangements for our executive officers and other senior management;

- reviewing, evaluating and recommending to the Board succession plans for our executive officers; and

- reviewing and establishing general policies relating to compensation and benefits of our employees, including our overall compensation strategy, including base salary, incentive compensation and equity-based grants, to assure that it promotes stockholder interests and supports our strategic and tactical objectives, and that it provides for appropriate rewards and incentives for our management and employees.

Nominating and Corporate Governance Committee

Our Nominating and Corporate Governance Committee consists of Patrick Machado, Sapna Srivastava and Zhengbin Yao. The chair of our Nominating and Corporate Governance Committee is Sapna Srivastava. The Board has determined that each member of the Nominating and Corporate Governance Committee is independent under the Nasdaq Listing Rules.

Specific responsibilities of our Nominating and Corporate Governance Committee include:

- identifying and evaluating candidates, including the nomination of incumbent directors for reelection and nominees recommended by stockholders, to serve on the Board;

- considering and making recommendations to the Board regarding the composition and chairmanship of the committees of the Board;

- instituting plans or programs for the continuing education of the Board and orientation of new directors;

- developing and making recommendations to the Board regarding corporate governance guidelines and matters; and

- overseeing periodic evaluations of the Board's performance, including committees of the Board and management.

Code of Business Conduct and Ethics

We have adopted a Code of Business Conduct and Ethics that applies to all employees, officers and directors. This includes our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The full text of our Code of Business Conduct and Ethics is posted on our website at www.alumis.com. We intend to disclose on our website any future amendments to our Code of Business Conduct and Ethics or waivers that exempt any principal executive officer, principal financial officer, principal accounting officer or controller, persons performing similar functions or our directors from provisions in the Code of Business Conduct and Ethics.

Insider Trading Policy

We have adopted an insider trading policy applicable to our directors, officers and employees and other covered persons, governing the purchase, sale and other dispositions of our securities (the "Insider Trading Policy"). We believe that the Insider Trading Policy is reasonably designed to promote compliance with applicable U.S. insider trading laws, rules and regulations, and listing standards applicable to us. The Insider Trading Policy is filed as Exhibit 19.1 to our 2024 Annual Report on Form 10-K for the fiscal year ended December 31, 2024.

Compensation Committee Interlocks and Insider Participation

Each member of our Compensation Committee is a "non-employee" director within the meaning of Rule 16b-3 of the rules promulgated under the Exchange Act and independent within the meaning of the independent director guidelines of Nasdaq. None of the members of our Compensation Committee was or is one of our officers or employees, and none of our executive officers serves as a member of the board of directors or compensation committee of any entity that has one or more executive officers who serves on the Board or the Compensation Committee.

Our Executive Officers

The following table presents certain information with respect to our executive officers as of March 19, 2026.

Name	Age	Position
Martin Babler	61	President and Chief Executive Officer, Chairman of the Board
Mark Bradley	61	Chief Development Officer
Jörn Drappa, M.D., Ph.D.	61	Chief Medical Officer
David M. Goldstein, Ph.D.	60	Chief Scientific Officer
Roy Hardiman	66	Chief Business and Strategy Officer
John Schroer	60	Chief Financial Officer
Sanam Pangali	42	Chief Legal Officer and Corporate Secretary

Martin Babler. Biographical information regarding Mr. Babler is set forth above under "—Our Board of Directors."

Mark Bradley has served as our Chief Development Officer since May 2021. From November 2020 to March 2021, Mr. Bradley served as Senior Vice President and Site Head at The Bristol-Myers Squibb Company, a biopharmaceutical

company, after its acquisition of MyoKardia, Inc., a precision medicine company focused on treating cardiovascular diseases, in November 2020. From November 2017 to November 2020, Mr. Bradley held roles of increasing responsibility at MyoKardia, most recently as Senior Vice President, Development. From 2004 to 2017, Mr. Bradley held roles of increasing responsibility at Genentech, Inc., a biopharmaceutical company, most recently as Head, Business Management gRED Clinical Operations. Mr. Bradley began his career at UCSF in public health research. Mr. Bradley received an M.A. and B.A. from University of California, Berkeley.

Jörn Drappa, M.D., Ph.D., has served as our Chief Medical Officer and Head of Research and Development since September 2022. From February 2018 to March 2021, Dr. Drappa served as the Chief Medical Officer and Head of Research and Development at Viela Bio, Inc., a biotechnology company. From May 2011 to February 2018, Dr. Drappa served in various roles at MedImmune, the biologics division of AstraZeneca plc, including as Vice President of Clinical Development. From August 2008 to May 2011, Dr. Drappa served as Senior Medical Director for the Inflammation and Autoimmune assets at Genentech, Inc., a biopharmaceutical company. Dr. Drappa received his M.D. and a Ph.D. from the University of Cologne in Germany. He performed his postgraduate studies at Cornell Medical School/Hospital for Special Surgery, followed by residency at New York Hospital and rheumatology fellowship at the Hospital for Special Surgery.

David M. Goldstein, Ph.D., has served as our Chief Scientific Officer since September 2021. From September 2020 to September 2021, Dr. Goldstein served as Site Head and Chief Scientific Officer of Principia Biopharma Inc., a biopharmaceutical company acquired by Sanofi S.A.in September 2020. From March 2016 to September 2020, Dr. Goldstein served in various roles at Principia Biopharma Inc., including as the Chief Scientific Officer from March 2016 to September 2020. From July 1994 to February 2011, Dr. Goldstein held positions of increasing responsibility at Roche Holding AG, a pharmaceutical company, most recently serving as Senior Director, Medicinal Chemistry and Head of Inflammation Chemistry. Dr. Goldstein was also previously a Consulting Assistant Professor at Stanford University. Dr. Goldstein received a Ph.D. in chemistry from the University of Virginia and a B.A. in chemistry from Franklin and Marshall College.

Roy Hardiman has served as our Chief Business and Strategy Officer since January 2025, Chief Business Officer since September 2024, and as Chief Business and Legal Officer from September 2021 to September 2024. From January 2015 to September 2020, Mr. Hardiman served as the Chief Business Officer and Chief Legal Officer of Principia Biopharma Inc., a biotechnology company acquired by Sanofi S.A.in 2020. From 2010 to 2012, Mr. Hardiman was a director of Pharmacyclics Inc., a biopharmaceutical company, and chaired its Nominating and Corporate Governance Committee. From 1990 to 2009, Mr. Hardiman held leadership positions at Genentech, Inc., a biopharmaceutical company, including Vice President of Alliance Management, Vice President, Corporate Law and Assistant Secretary, Director and Far East Representative, Business Development. From 1987 to 1990, Mr. Hardiman was an attorney at Morrison & Foerster LLP. Mr. Hardiman received his J.D. from University of California, Los Angeles School of Law, his M.A. in Biology and his B.A. in pharmacology from University of California, Santa Barbara.

John Schroer has served as our Chief Financial Officer since May 2022. From February 2021 to February 2022, Mr. Schroer served as Chief Financial Officer at ArsenalBio Inc., a biotechnology company. From May 2018 to December 2020, Mr. Schroer served as Chief Financial Officer and Treasurer at Translate Bio, Inc., a biotechnology company acquired by Sanofi S.A. in 2021. From January 2014 to April 2018, Mr. Schroer served as a director and sector head — healthcare at Allianz Global Investors, a global asset management company. From 2009 to December 2013, Mr. Schroer served as President and Chief Investment Officer at Schroer Capital, LP, a financial services company that he founded. Mr. Schroer received a B.S. in History and International Relations and an M.B.A. from the University of Wisconsin-Madison.

Sanam Pangali, J.D., has served as our Chief Legal Officer since July 2025. Prior to this, she held the role of Senior Vice President, Legal from September 2024 to July 2025. From November 2022 to September 2024, Ms. Pangali served in various leadership roles at ACELYRIN, Inc., including as Chief Legal Officer and Head of People from May 2024 to September 2024, Senior Vice President, Corporate Legal from October 2023 to May 2024 and Vice President, Corporate Legal from November 2022 to October 2023. Previously, Ms. Pangali was General Counsel at Snapdocs, Inc. from 2020 to 2021 and from 2019 through its acquisition by Sanofi S.A. in 2020, she served as Senior Director & Associate General Counsel at Principia Biopharma Inc. Between 2013 and 2019, Ms. Pangali held in-house legal roles after beginning her legal career in the Business & Finance practice groups at Morrison & Foerster LLP. Ms. Pangali earned her J.D. from the University of

Pennsylvania Carey Law School and holds a B.A. in Political Science, with a minor in Economics, from the University of California, San Diego.

Item 11: Executive Compensation

Our named executive officers, including our principal executive officer and the two most highly compensated executive officers, as of December 31, 2025, were:

- Martin Babler, our President and Chief Executive Officer;
- David M. Goldstein, Ph.D., our Chief Scientific Officer; and
- Jörn Drappa, our Chief Medical Officer.

Summary Compensation Table

The following table presents information concerning the compensation of our named executive officers for the years ended December 31, 2025 and 2024, as applicable:

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	Total ($)
Martin Babler					
President, Chief Executive Officer and Director	2025	680,830	4,743,220	524,239	5,948,289
	2024	605,900	9,748,581	306,738	10,661,219
David M. Goldstein, Ph.D.					
Chief Scientific Officer	2025	526,401	1,187,353	294,785	2,008,539
	2024	466,500	2,593,094	184,868	3,244,462
Jörn Drappa, M.D., Ph.D.					
Chief Medical Officer	2025	523,755	1,161,607	293,303	1,978,665

(1) Amounts reflect the aggregate grant date fair value of option awards granted to our named executive officers, computed in accordance with FASB ASC 718. Such amounts for 2024 also include the incremental fair value of $161,437 and $36,473, for Messrs. Babler and Goldstein, respectively, resulting from the modification of certain stock options on March 29, 2024, which reduced the exercise price of certain outstanding stock options held by Messrs. Babler and Goldstein, to $8.84. The incremental fair value was computed in accordance with FASB ASC 718 as the excess of the fair value of the modified awards over the fair value of the original awards immediately before the modification, based on the assumptions used for financial reporting purposes. The assumptions used in calculating the grant date fair value of the option awards reported in this column are set forth in Note 12 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

(2) The amounts disclosed represent annual performance bonuses. For more information, see the description of the annual performance bonuses in the subsection titled "—Narrative to the Summary Compensation Table—Annual Performance Bonus Opportunity" below.

Narrative to the Summary Compensation Table

Historically, our Board has been responsible for overseeing all aspects of our executive compensation programs. In making compensation determinations, 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.

Our Board has historically determined our executive officers' compensation and has typically reviewed and discussed management's proposed compensation with our chief executive officer for all executives other than our chief executive officer. Based on those discussions and its discretion, our Board has then approved the compensation of each executive officer.

Annual Base Salary

Base salaries for our executive officers are initially established through arm's-length negotiations at the time of the executive officer's hiring, taking into account such named executive officer's qualifications, experience, the scope of his or her responsibilities and competitive market compensation paid by other companies for similar positions within the industry and geography. Base salaries are reviewed periodically, and adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance and experience.

The 2025 annual base salaries for our named executive officers are set forth in the table below.

Name	2025 Base Salary ($)
Martin Babler	680,830
David M. Goldstein, Ph.D.	526,401
Jörn Drappa, M.D., Ph.D.	523,755

2025 Annual Performance Bonus Opportunity

Our executive officers are eligible to earn an annual incentive bonus of up to a percentage of such executive officer's annual base salary, based on the achievement of pre-established performance objectives determined by the Board.

For 2025, each of Mr. Babler, Dr. Goldstein and Dr. Drappa was eligible to receive a target bonus equal to 55%, 40% and 40% of their base salary, respectively, based on the achievement of certain corporate goals. In January 2026, the Board determined that the 2025 corporate goals were achieved at 140%. As a result, the Board approved annual performance bonuses for Mr. Babler, Dr. Goldstein and Dr. Drappa in the amounts of $524,239, $294,785 and $293,303, respectively, as reported in the "Non-Equity Incentive Plan Compensation" column of the Summary Compensation Table above.

Equity-Based Incentive Awards

Our equity award program is the primary vehicle for offering long-term incentives to our executive officers. We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. To date, we have used stock option grants and RSUs for this purpose because we believe they are an effective means by which to align the long-term interests of our executive officers with those of our stockholders. We believe that our equity awards are an important retention tool for our executive officers, as well as for our other employees. Grants to our executive officers and other employees are made at the discretion of the Board and are not made at any specific time period during a year.

2025 Option Awards

During the fiscal year ended December 31, 2025, we granted options to each of our named executive officers, as shown in more detail in the "Outstanding Equity Awards at Fiscal Year End" table below.

Outstanding Equity Awards at Fiscal Year End

The following table presents the outstanding equity awards held by each named executive officer as of December 31, 2025.

		Option Awards[1]					Stock Awards	
Name	Grant Date	Number of Securities Underlying Unexercised Options Exercisable (#)	Number of Securities Underlying Unexercised Options Unexercisable (#)	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price Per Share ($)[2]	Option Expiration Date	Number of Shares or Units of Stock that Have Not Vested (#)	Market Value of Shares or Units of Stock that Have Not Vested ($)
Martin Babler.	9/15/2021	380,852 [3]	—	—	3.83	9/14/2031	—	—
	1/27/2022	106,951 [4][5]	2,229	—	8.84	1/26/2032	—	—
	1/27/2022	534,759 [6][7]	186,609	—	8.84	1/26/2032	—	—
	6/22/2023	263,101 [8][9]	93,182	—	8.84	6/22/2033	—	—
	10/9/2023	107,028 [10][11]	49,055	—	8.84	10/8/2033	—	—
	3/29/2024	241,210 [12][13]	135,681	—	8.84	3/28/2034	—	—
	5/6/2024	—	—	478,288 [14]	10.19	5/5/2034	—	—
	6/6/2024	245,989 [15][16]	153,742	—	13.32	6/5/2034	—	—
	6/27/2024	8,021 [17]	13,369 [17]	—	16.00	6/26/2034	—	—
	2/18/2025	—	523,000 [18]	—	5.06	2/17/2035	—	—
	7/29/2025	—	662,000 [19]	—	3.95	7/28/2035	—	—
	7/29/2025	—	150,000 [19]	—	3.95	7/28/2035	—	—
David M. Goldstein, Ph.D.	1/27/2022	171,122 [6][20]	59,715	—	8.84	1/26/2032	—	—
	1/27/2022	42,780 [4][21]	892	—	8.84	1/26/2032	—	—
	6/22/2023	11,978 [8][22]	5,303	—	8.84	6/22/2033	—	—
	10/9/2023	30,642 [10][23]	14,045	—	8.84	10/8/2033	—	—
	6/6/2024	53,475 [15][24]	33,422	—	13.32	6/5/2034	—	—
	5/6/2024	—	—	206,074 [14]	10.19	5/5/2034	—	—
	2/18/2025	—	180,000 [18]	—	5.06	2/17/2035	—	—
	7/29/2025	—	107,950 [19]	—	3.95	7/28/2035	—	—
	7/29/2025	—	—	—	—	—	27,000 [25]	263,520 [26]
Jörn Drappa, M.D., Ph.D. .	8/29/2022	171,122 [27][28]	28,521	—	8.84	8/29/2032	—	—
	8/29/2022	85,561 [29][30]	38,218	—	8.84	8/29/2032	—	—
	6/22/2023	12,834 [8][31]	4,546	—	8.84	6/22/2033	—	—
	10/9/2023	18,652 [10][32]	8,549	—	8.84	10/8/2033	—	—
	3/29/2024	54,545 [12][33]	30,682	—	8.84	3/28/2034	—	—
	5/6/2024	—	—	70,802 [14]	10.19	5/5/2034	—	—
	6/6/2024	64,171 [15][34]	40,107	—	13.32	6/5/2034	—	—
	6/27/2024	2,005 [17]	3,342 [17]	—	16.00	6/26/2034	—	—
	2/18/2025	—	180,000 [18]	—	5.06	2/17/2035	—	—
	7/29/2025	—	101,850 [19]	—	3.95	7/28/2035	—	—
	7/29/2025	—	—	—	—	—	25,450 [25]	248,392 [26]

(1) All of the option awards prior to our IPO were granted under the 2021 Plan or our 2024 POP, and all of the option awards following our IPO were granted under our 2024 EIP.

(2) Except for Mr. Babler's option award with a grant date of September 15, 2021, the exercise price of each of these options granted prior to March 29, 2024 was repriced to $8.84 per share in March 2024.

(3) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the

September 15, 2021 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer. As of December 31, 2025, all shares have vested.

(4) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the January 27, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer.

(5) As of December 31, 2025, 104,722 shares have vested.

(6) Stock option award vests over a period of six years with 1/3rd of the shares underlying the option vesting on the second anniversary of the January 27, 2022 vesting commencement date and 1/48th of the remaining shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer.

(7) As of December 31, 2025, 348,150 shares have vested.

(8) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the May 22, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer.

(9) As of December 31, 2025, 169,919 shares have vested.

(10) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the October 9, 2023 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. The option award includes an early exercise feature.

(11) As of December 31, 2025, 57,973 shares have vested.

(12) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the March 29, 2024 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer.

(13) As of December 31, 2025, 105,529 shares have vested.

(14) Stock option award vests on the first date upon which both the performance-based condition (the "Performance Condition") and the service-based condition (the "Service Condition") are satisfied with respect to such shares. The Performance Condition shall be satisfied as to: (i) 1/3 of the shares underlying the option if, on a date prior to the date that is four years following the vesting commencement date, the volume-weighted average price per share of common stock on the Nasdaq Stock Market for a period of 30-consecutive trading days (the "Share Price") equals or exceeds $46.75 (the "$46.75 Shares"); (ii) 1/3 of shares underlying the option, plus the $46.75 Shares to the extent such shares have not yet satisfied the Performance Condition, if, on a date prior to the date that is five years following the vesting commencement date, the Share Price equals or exceeds $70.125 (the "$70.125 Shares"); and (iii) 1/3 of shares underlying the option, plus the $46.75 Shares and $70.125 Shares, to the extent such shares have not yet satisfied the Performance Condition, if, on a date prior to the date that is six years following the vesting commencement date, the Share Price equals or exceeds $93.50 (the "$93.50 Shares") (each of (i), (ii) and (iii), a "Performance Target"). The Service Condition will be satisfied as to 1/36th of each of the $46.75 Shares, the $70.125 Shares, and the $93.50 Shares on a monthly basis following the vesting commencement date, in each case subject to the optionholder's continued service through each such date. The option award includes an early exercise feature and is subject to certain post-termination and acceleration benefits as described above in the subsection titled "— Potential Payments and Benefits upon Termination or Change in Control — POP Options."

(15) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the June 6, 2024 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer.

(16) As of December 31, 2025, 92,247 shares have vested.

(17) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the June 21, 2024 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

(18) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the February 18, 2025 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

(19) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the July 29, 2025 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date.

(20) As of December 31, 2025, 111,407 shares have vested.

(21) As of December 31, 2025, 41,888 shares have vested.

(22) As of December 31, 2025, 6,675 shares have vested.

(23) As of December 31, 2025, 16,597 shares have vested.

(24) As of December 31, 2025, 20,053 shares have vested.

(25) Restricted stock unit award vests over a period of four years with 25% of the shares underlying the RSU vesting on August 1, 2026 and 1/16th of the shares underlying the RSU vesting on a quarterly basis thereafter, subject to continued service through each vesting date.

(26) Amount calculated by multiplying the number of shares shown in the table by $9.76, the closing market price of our common stock on Nasdaq as of December 31, 2025, the last trading day of our fiscal year.

(27) Stock option award vests over a period of four years with 25% of the shares underlying the option vesting on the first anniversary of the August 22, 2022 vesting commencement date and 1/48th of the shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer.

(28) As of December 31, 2025, 142,601 shares have vested.

(29) Stock option award vests over a period of six years with 1/3rd of the shares underlying the option vesting on the second anniversary of the August 22, 2022 vesting commencement date and 1/48th of the remaining shares underlying the option vesting on a monthly basis thereafter, subject to continued service through each vesting date. This option is early exercisable and to the extent any of such shares are unvested as of a given date, any purchased shares will remain subject to a right of repurchase by us upon the termination of the service of the named executive officer.

(30) As of December 31, 2025, 47,343 shares have vested.

(31) As of December 31, 2025, 8,288 shares have vested.

(32) As of December 31, 2025, 10,103 shares have vested.

(33) As of December 31, 2025, 23,863 shares have vested.

(34) As of December 31, 2025, 24,064 shares have vested.

Awards held by our named executive officers may be eligible for accelerated vesting under specified circumstances, as described in more detail below under the subsection titled "—Potential Payments and Benefits upon Termination or Change in Control."

We may in the future, on an annual basis or otherwise, grant additional equity awards to our executive officers pursuant to our 2024 EIP.

Employment Agreements

Offer Letters

Below are descriptions of our offer letters with our named executive officers. For a discussion of the severance pay and other benefits to be provided in connection with a termination of employment and/or a change in control under the arrangements with our named executive officers, please see the subsection titled "—Potential Payments and Benefits upon Termination or Change in Control." Each of our named executive officers is employed at will.

Mr. Babler. In September 2021, we and Mr. Babler entered into an offer letter that governs the terms of Mr. Babler's employment with us. Pursuant to the agreement, Mr. Babler's employment is at will. Mr. Babler is also entitled to certain severance benefits, the terms of which are described below under the subsection titled "—Potential Payments and Benefits upon Termination or Change in Control."

Dr. Goldstein. In September 2021, we and Dr. Goldstein entered into an offer letter that governs the terms of Dr. Goldstein's employment with us. Pursuant to the agreement, Dr. Goldstein's employment is at will. Dr. Goldstein is also entitled to certain severance benefits, the terms of which are described below under the subsection titled "—Potential Payments and Benefits upon Termination or Change in Control."

Dr. Drappa. In June 2024, we and Dr. Drappa entered into an offer letter that governs the terms of Dr. Drappa's employment with us. Pursuant to the agreement, Dr. Drappa's employment is at will. Dr. Drappa is also entitled to certain severance benefits, the terms of which are described below under the subsection titled "—Potential Payments and Benefits

upon Termination or Change in Control."

Potential Payments and Benefits upon Termination or Change in Control

Regardless of the manner in which a named executive officer's service terminates, each named executive officer is entitled to receive unpaid salary earned during his term of service.

Severance and Change in Control Plan

In February 2025, our Compensation Committee adopted our Severance and Change in Control Plan (the "Severance Plan"). The Severance Plan provides for the payment of severance and/or benefits to participants upon a qualifying termination of employment ("Covered Termination"), consisting of either (a) termination of a participant by us without cause (as defined in the Severance Plan) and other than as a result of the participant's death or disability or (b) the participant's resignation for good reason (as defined in the Severance Plan).

If a named executive officer experiences a Covered Termination within 12 months following completion of a change in control (as defined in the Severance Plan) (such period, the "Change in Control Period"), such named executive officer shall be eligible to receive the following benefits: (a) a lump sum cash payment equal to 12 months (or in Mr. Babler's case, 18 months) of base salary (as defined in the Severance Plan); (b) a lump sum cash payment equal to 1.00x to (or in Mr. Babler's case, 1.50x) the named executive officer's target bonus (as defined in the Severance Plan) for the calendar year in which the named executive officer's Covered Termination occurs; (c) COBRA premium payments paid by us for the named executive officer and the named executive officer's eligible dependents for a period not exceeding the earliest of (1) 12 months (or in Mr. Babler's case, 18 months) following the date of the named executive officer's Covered Termination, (2) expiration of the named executive officer's eligibility for continuation coverage under COBRA, or (3) the date when the named executive officer becomes eligible for a substantially equivalent health insurance coverage in connection with new employment; and (d) full acceleration of any outstanding, unvested equity awards held by the named executive officer.

If a named executive officer experiences a Covered Termination outside of the Change in Control Period, such named executive officer will be eligible to receive (a) cash payments in an amount equal to nine months (or in Mr. Babler's case, 12 months) of base salary, to be paid in accordance with our regular payroll practices over the length of such period; (b) a pro-rated amount of the named executive officer's target bonus based upon the number of days worked in the calendar year in which such named executive officer's Covered Termination occurs, payable in a lump sum no later than the date that all of our other executives would regularly receive the bonus payment; and (c) COBRA premiums paid by us for the named executive officer and named executive officer's eligible dependents for a period not exceeding nine months (or in Mr. Babler's case, 12 months).

In addition, as described below, our named executive officers are eligible to receive (a) acceleration of certain outstanding, unvested equity awards granted before the adoption of the Severance Plan pursuant to their offer letters and (b) acceleration of their POP Options (as defined below).

Each named executive officer's right to receive the payments and benefits provided under the Severance Plan are subject to such named executive officer's execution, delivery and non-revocation of a separation agreement containing, among other provisions, a general release of all claims in favor us, our subsidiaries and our affiliates.

Offer Letters with Named Executive Officers

Pursuant to each named executive officer's offer letter, if (a) his employment is terminated without cause (as defined in the offer letter) or (b) in the event of his constructive termination (as defined in the offer letter), then the named executive officer will be entitled to receive acceleration of his then-unvested equity awards that were granted before the adoption of the Severance Plan as to the number of shares underlying such awards that would have been vested as of the first anniversary of the date of his termination, with such acceleration to be effective immediately prior to his termination. These severance benefits are conditioned upon the named executive officer's delivery of a general release of claims in our favor.

Upon a change of control (as defined in the offer letter) other than an excluded change of control (as defined in the offer letter), 50% of the then-unvested portions of the equity awards that were granted to the named executive officer before the adoption of the Severance Plan will accelerate.

POP Options

Certain benefits apply to the options granted on May 6, 2024, to each of Mr. Babler, Dr. Goldstein and Dr. Drappa, (the "POP Options") under our 2024 POP. If the officer voluntarily resigns, the POP Options that have satisfied the service condition at the time of termination will remain outstanding and be eligible to vest for one year post-termination if the performance condition(s) with respect to such options are satisfied during the one year post-termination period. If the officer is terminated without cause or by constructive termination (as defined in the 2024 POP), the POP Options that have satisfied the service condition at the time of termination will remain outstanding and be eligible to vest for two years post-termination if the performance condition(s) with respect to such shares are satisfied during the two years post-termination period.

Upon a change in control (as defined in the 2024 POP), with respect to any portion of the performance condition(s) not yet satisfied, if the value of the property expected to be received by our stockholders as a result of such change in control equals or exceeds the applicable share price performance target, a number of shares subject to the POP Options will satisfy the performance condition with respect to such share price performance target as of immediately prior to the change in control.

Additionally, the service condition will be satisfied with respect to 100% of the POP Options immediately prior to a change in control if the officer (i) remains in continuous service through the change in control or (ii) is terminated without cause or by constructive termination prior to a change in control and the change in control occurs within one year following such termination. If the officer is terminated without cause or by constructive termination outside of a change in control, the service-based vesting condition will be satisfied as to an additional 1/3 of shares subject to each of the share price performance targets (see the subsection titled "—Outstanding Equity Awards at Fiscal Year End").

Pension Benefits

Our named executive officers did not participate in, or otherwise receive any benefits under, any pension or retirement plan sponsored by us during the year ended December 31, 2025.

Nonqualified Deferred Compensation

Our named executive officers did not participate in, or earn any benefits under, a non-qualified deferred compensation plan sponsored by us during the year ended December 31, 2025.

Other Compensation and Benefits

All of our current named executive officers are eligible to participate in our employee benefit plans, in each case on the same basis as all of our other employees. These employee benefit plans include medical, dental, vision, disability, employee assistance, life, accidental death and dismemberment insurance plans. We pay the premiums for the medical, dental, vision, life and accidental death and dismemberment insurance for all of our employees, including our named executive officers. We generally do not provide perquisites or personal benefits to our named executive officers. In addition, we provide the opportunity to participate in a 401(k) plan to our employees, including each of our named executive officers, as discussed in the subsection titled "—401(k) Plan" below.

401(k) Plan

Our named executive officers are eligible to participate in our defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may elect to defer up to 15% of their eligible compensation into the plan on a pretax or after tax basis, up to annual limits prescribed by the Internal Revenue Code of 1986, as amended. Our Board approved a Company match on 100% of each participant's

employee deferral contributions up to 3% of eligible compensation and a 50% match on each participant's employee deferral contributions from 3% to 5% of eligible compensation, effective from January 1, 2026.

Compensation Recovery ("Clawback") Policy

In June 2024, the Board adopted a compensation recovery policy in accordance with the Dodd-Frank Wall Street Reform and Consumer Protection Act and applicable Nasdaq rules, a copy of which was filed as Exhibit 97.1 to our 2024 Annual Report on Form 10-K.

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 stock options to our employees, including our named executive officers. Historically, we have granted new-hire option awards monthly after a new hire's employment start date and annual refresh employee option grants in the first quarter of each fiscal year, which refresh grants are typically approved by either the Equity Grant Committee described below (except for grants to certain senior employees, including our executive officers) or the Compensation Committee in its regularly scheduled meeting occurring in such quarter. Also, 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, at the time of each annual meeting of our stockholders, and on specifically designated dates for any director who elects to receive some or all of their eligible cash compensation in the form of stock options, pursuant to the Non-Employee Director Compensation Policy, as further described under the heading, "Non-Employee Director Compensation — Non-Employee Director Compensation Policy" below. Other than the delegation by the Board to an Equity Grant Committee of the approval of the issuance of certain equity-based awards to employees and consultants under the 2024 Plan, which awards are typically granted on a monthly basis on the tenth of each month, 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 us when determining the timing of stock option grants and does not seek to time the award of stock options in relation to our public disclosure of MNPI. We have not timed the release of MNPI for the purpose of affecting the value of executive compensation.

Non-Employee Director Compensation

The following table presents the compensation awarded to or earned by or paid to all individuals who served as non-employee directors during the year ended December 31, 2025. Dr. Colowick and Dr. Tananbaum voluntarily waived all compensation for their service as a director during the year ended December 31, 2025. Mr. Babler, our President and Chief Executive Officer, is also a member of our Board but did not receive any additional compensation for his service as a director. The compensation of Mr. Babler is set forth in the subsection titled "—Summary Compensation Table" above.

Name	Fees Earned or Paid in Cash ($)	Option Awards [1]	Total
Srinivas Akkaraju, Ph.D.	52,651	161,307	213,958
Alan B. Colowick, M.D., M.P.H.	—	—	—
Patrick Machado, J.D.	65,000	161,307	226,307
Sapna Srivastava, Ph.D.	64,423	161,307	225,730
James B. Tananbaum, M.D.	—	—	—
Lynn Tetrault, J.D.[2]	28,832	161,307	190,139
Zhengbin Yao, Ph.D.	51,360	161,307	212,667

(1) The amounts reported in this column reflect the aggregate grant date fair value of the stock options granted to the non-employee director during the year ended December 31, 2025, computed in accordance with FASB ASC 718, and do not reflect dollar amounts actually received by the non-employee director or the economic value that may be received by the non-employee director upon stock option exercise or any sale of the underlying shares of common stock. The assumptions used in calculating the grant date fair value of the option awards reported in this column are set forth in Note 12 to our consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

(2) Ms. Tetrault commenced service on our Board on May 23, 2025.

The table below presents the aggregate number of shares subject to outstanding stock options, as of December 31, 2025, beneficially owned by each of our non-employee directors for the year ended December 31, 2025.

Name	Number of Shares Underlying Outstanding Options as of December 31, 2025
Srinivas Akkaraju, Ph.D.	49,800
Alan B. Colowick, M.D., M.P.H.	—
Patrick Machado, J.D.	218,184
Sapna Srivastava, Ph.D.	108,623
James B. Tananbaum, M.D.	—
Lynn Tetrault, J.D.[(1)]	114,131
Zhengbin Yao, Ph.D.	85,094

(1) Ms. Tetrault commenced service on our Board on May 23, 2025.

Non-Employee Director Compensation Policy

In February 2025, our Board adopted an amended and restated non-employee director compensation policy applicable to all of our non-employee directors. In July 2025, the Board amended and restated this policy. The amended and restated policy provides that each such non-employee director will receive the following compensation for service on our Board:

- an annual cash retainer of $40,000 (plus an additional $30,000 for the non-executive chair of our Board and $25,000 for the non-executive lead independent director of our Board);
- an additional annual cash retainer of $10,000, $7,500, $5,000 and $5,000 for service as a member of the Audit Committee, Compensation Committee, the Nominating and Corporate Governance Committee and Science and Technology Committee, respectively;
- an additional annual cash retainer of $20,000, $15,000, $10,000 and $10,000 for service as chair (in lieu of the additional annual cash retainer or services as a member) of the Audit Committee, Compensation Committee, the Nominating and Corporate Governance Committee, and the Science and Technology Committee, respectively;
- an initial option grant to purchase 99,600 shares of our common stock on the date of each such non-employee director's appointment to our Board; and
- an annual option grant to purchase 49,800 shares of our common stock on the date of each of our annual stockholder meetings.

Each of the option grants described above under the non-employee director compensation policy will be granted under our 2024 EIP. Each initial option grant will vest over a three-year period, with $1/36^{th}$ of the shares vesting in equal monthly installments following the date of grant, such that the option is fully vested on the third anniversary of the date of grant, subject to the director's continuous service to us through each such vesting date. The initial grant will vest in full upon a Change in Control (as defined in the 2024 EIP), subject to the director's continuous service to us through such date. Each annual option grant will vest and become exercisable subject to the director's continuous service to us through the earlier of the first anniversary of the date of grant or the next annual stockholder meeting. The annual grant will also vest in full upon a Change in Control (as defined in the 2024 EIP), subject to the director's continuous service to us through such date. The term of each option will be 10 years, subject to earlier termination as provided in the 2024 EIP.

We have reimbursed and will continue to reimburse all of our non-employee directors for their reasonable out-of-pocket expenses incurred in attending board of directors and committee meetings.

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

Equity Compensation Plan Information

The following table shows certain information with respect to all of 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[1] (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)[2]	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (a))[3] (c)
Equity compensation plans approved by stockholders	22,880,475	8.69	7,382,841
Equity compensation plans not approved by stockholders	—	—	—
Total	22,880,475	8.69	7,382,841

(1) Consists of outstanding awards under the 2021 Plan, the 2024 POP, the 2024 EIP and the ACELYRIN Plans. Excludes purchase rights accruing under our 2024 ESPP. Each offering under the 2024 ESPP consists of one six-month purchase period, and eligible employees may purchase shares of our common stock at a price equal to 85% of the fair market value of our common stock on the first or last day of the offering period, whichever is lower.

(2) Represents the weighted-average exercise price of outstanding options. Because RSUs do not have an exercise price, the weighted-average exercise price does not take into account outstanding RSUs.

(3) As of December 31, 2025, 7,382,841 shares of common stock remained available for future issuance under the 2024 EIP, the 2024 POP and the ACELYRIN Plans. Excludes 805,334 shares of common stock available for future issuance under the 2024 ESPP as of December 31, 2025. The number of shares remaining available for future issuance under the 2024 EIP automatically increases on January 1st each year, through and including January 1, 2034, in an amount equal to 5% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, or a lesser number of shares as determined by our Board prior to January 1st of a given year. On January 1, 2026, the number of shares available for issuance under the 2024 EIP automatically increased by 5,235,338 shares of our common stock. The number of shares remaining available for future issuance under the 2024 ESPP automatically increases on January 1st of each year through and including January 1, 2034, in an amount equal to the least of (i) 1% of the total number of shares of our common stock outstanding on December 31st of the preceding calendar year, (ii) 1,950,000 shares of our common stock, or (iii) a number of shares as determined by the Board prior to January 1st of a given year. On January 1, 2026, the number of shares available for issuance under the 2024 ESPP automatically increased by 1,047,067 shares of our common stock.

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth information regarding beneficial ownership of our capital stock as of March 1, 2026 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of its common stock;
- each of our directors;
- each of our named executive officers identified in Item 11 of this Annual Report on Form 10-K; and
- all of our current executive officers and directors as a group.

We have determined beneficial ownership in accordance with the rules and regulations of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Except as indicated by the footnotes below, we believe, based on information furnished to us, that the persons and entities named in the table below have sole voting and sole investment power with respect to all shares that they beneficially own, subject to applicable community property laws.

Applicable percentage ownership is based on 123,115,602 shares of our common stock and 4,059,908 shares of our non-voting common stock outstanding as of March 1, 2026. We have deemed the number of shares of common stock that a

person has the right to acquire within 60 days after the date of this table (which includes the number of shares of non-voting common stock owned by such person to the extent they can be converted to common stock within 60 days after the date of this table), to be outstanding and to be beneficially owned by the person for the purpose of computing the percentage ownership of that person. We do not deem these shares outstanding, however, for the purpose of computing the percentage ownership of any other person.

The table below does not reflect 4,059,908 shares of non-voting common stock held by affiliated holders subject to an ownership limitation in our amended and restated certificate of incorporation that prevents the conversion of such shares if, upon conversion, the converting holder and its affiliates would beneficially own in the aggregate, directly or indirectly, shares of voting common stock in excess of 4.99% of all shares outstanding at such time. The restriction can be waived by the holders upon 61 days' prior written notice to us.

Unless otherwise indicated, the address for each beneficial owner listed in the table below is c/o Alumis Inc., 280 East Grand Avenue, South San Francisco, CA 94080.

	Voting Common Stock	
Name of Beneficial Owner	Number of Shares Beneficially Owned	% of Total Voting Power
Greater than 5% Stockholders:		
AyurMaya Capital Management Fund, LP[1]	15,139,707	12.3 %
Entities affiliated with Foresite Capital Management[2]	16,189,804	13.2 %
Samsara BioCapital, L.P.[3]	6,345,219	5.2 %
Directors and Named Executive Officers:		
Martin Babler[4]	2,631,015	2.1 %
David M. Goldstein, Ph.D.[5]	790,191	*
Jörn Drappa, M.D., Ph.D.[6]	536,675	*
Srinivas Akkaraju, M.D., Ph.D.[3]	6,345,219	5.2 %
Alan Colowick, M.D., M.P.H.[7]	15,158,111	12.3 %
Patrick Machado, J.D.[8]	150,115	*
Sapna Srivastava, Ph.D.[9]	39,572	*
James B. Tananbaum, M.D.[2]	16,189,804	13.2 %
Lynn Tetrault, J.D.[10]	64,331	*
Zhengbin Yao, Ph.D.[11]	38,146	*
All directors and executive officers as a group (14 persons)[12]	43,851,485	34.1 %

* Represents beneficial ownership of less than 1%.

(1) Based solely on information contained in the Schedule 13D/A filed with the SEC on May 23, 2025 by AyurMaya Capital Management Company, LP (the "Investment Manager") and David E. Goel. The shares consist of 15,139,707 shares of common stock held by the AyurMaya Capital Management Fund, LP ("AyurMaya Fund"). The Investment Manager, a Delaware limited partnership, serves as the investment advisor to the AyurMaya Fund with respect to the securities directly held by the AyurMaya Fund. Mr. Goel serves as the Managing Member of AyurMaya Capital Management Company GP, LLC, the general partner of the Investment Manager, and may be deemed to possess shared voting and dispositive power with respect to the securities directly held by the AyurMaya Fund. Alan Colowick, a Senior Managing Director of Matrix Capital Management Company LP, an affiliate of the Investment Manager, serves on our Board. The business address for each of the AyurMaya Fund, the Investment Manager and Mr. Goel is c/o AyurMaya Capital Management LP, Bay Colony Corporate Center, 1000 Winter St., Suite 4500, Waltham, MA 02451.

(2) Based solely on information contained in the Schedule 13D/A filed with the SEC on January 12, 2026 by Foresite Capital Fund VI, L.P. ("Fund VI"), Foresite Capital Management VI, LLC ("FCM VI"), Foresite Capital Fund V, L.P. ("Fund V"), Labs Co-Invest V, LLC ("Labs Co-Invest"), Foresite Capital Management V, LLC ("FCM V"), Foresite Capital Opportunity Fund V, L.P. ("Opportunity Fund V"), Foresite Capital Opportunity Management V, LLC ("FCOM V"), Foresite Labs Fund I, L.P. ("Labs Fund I"), Foresite Labs Management I, LLC ("FLM I"), Foresite Labs Affiliates 2021, LLC ("Labs Affiliates"), Foresite Labs, LLC (Labs) and James B. Tananbaum. The shares consist of (i) 4,247,670 shares of common stock held by Fund VI, (ii) 5,702,536 shares of common stock held by Fund V, (iii) 194,459 shares held by Labs Co-Invest, (iv) 2,908,332

shares held by Opportunity Fund V, (v) 1,960,337 shares held by Labs Fund I, and (vi) 1,176,470 shares held by Labs Affiliates. James B. Tananbaum, M.D., is a member of our Board. FCM V is the general partner of Fund V and may be deemed to have sole voting and dispositive power over the shares held by Fund V; FCM VI is the general partner of Fund VI and may be deemed to have sole voting and dispositive power over the shares held by Fund VI; FCOM V is the general partner of Opportunity Fund V and may be deemed to have sole voting and dispositive power over the shares held by Opportunity Fund V; FCM V is the managing member of Labs Co-Invest and may be deemed to have sole voting and dispositive power over the shares held by Labs Co-Invest; Foresite Labs, LLC is the managing member of Labs Affiliates and may be deemed to have sole voting and dispositive power over the shares held by Labs Affiliates; and FLM I is the general partner of Labs Fund I and may be deemed to have sole voting and dispositive power over the shares held by Labs Fund I. Dr. Tananbaum is the managing member of FCM V, FCM VI, FCOM V and FLM I and may be deemed to have sole voting and dispositive power over shares held by Fund VI, Fund V, Labs Co-Invest, Opportunity Fund V and Labs Fund I. Dr. Tananbaum is the manager of Labs and the managing member of Labs Affiliates, and may be deemed to have sole voting and dispositive power over the shares held by Labs Affiliates. Each entity and Dr. Tananbaum disclaims beneficial ownership of these shares except to the extent of their respective pecuniary interests therein. The business address of Dr. Tananbaum and each of the entities listed above is 900 Larkspur Landing Circle, Suite 150, Larkspur, CA 94939.

(3) Based solely on information contained in the Schedule 13D/A filed with the SEC on January 13, 2026 by Samsara BioCapital, L.P. ("Samsara LP"), Samsara BioCapital GP, LLC ("Samsara GP"), Samsara Opportunity Fund, L.P. ("Samsara Opportunity Fund"), Samsara Opportunity Fund GP, LLC ("Samsara Opportunity GP") and Dr. Srinivas Akkaraju. The shares consist of (i) 4,491,731 shares of common stock held by Samsara LP and (ii) 1,853,488 shares of common stock held by Samsara Opportunity Fund. Samsara GP is the general partner of Samsara LP and Samsara Opportunity GP is the general partner of Samsara Opportunity Fund. Dr. Akkaraju is the managing member of Samsara GP and Samsara Opportunity GP and shares voting and investment authority over the shares held of Samsara LP and Samsara Opportunity Fund. Dr. Akkaraju is a member of our Board. The business address of Dr. Akkaraju and each of the entities listed above is 628 Middlefield Road, Palo Alto, CA 94301. Samsara GP and Samsara Opportunity Fund disclaims beneficial ownership in these shares except to the extent of its respective pecuniary interest therein.

(4) Consists of (i) 4,037 shares of common stock held of record by Mr. Babler, (ii) 106,454 shares of common stock held of record by the Martin Babler revocable trust UAD October 25, 2006, for which Martin Babler serves as a trustee and, (iii) 2,520,524 shares of common stock subject to options that are exercisable with 60 days of March 1, 2026. Mr. Babler holds sole voting and dispositive power with respect to the shares held by the Martin Babler revocable trust UAD October 25, 2006. Includes 478,288 shares of common stock subject to option awards granted under our 2024 POP that are early exercisable only upon satisfaction of the Performance Condition (as defined in Item 11 of this Annual Report on Form 10-K).

(5) Consists of (i) 4,389 shares of common stock held of record by Dr. Goldstein, (ii) 208,237 shares of common stock held of record by the Baily Goldstein Living Trust dated March 4, 2014, for which Dr. Goldstein serves as a trustee, (iii) 8,994 shares of common stock held of record by family members of Dr. Goldstein residing in his primary residence and (iv) 568,571 shares of common stock subject to options that are exercisable with 60 days of March 1, 2026. Dr. Goldstein holds shared voting and dispositive power with respect to the shares held by the Baily Goldstein Living Trust dated March 4, 2014. Includes 206,074 shares of common stock subject to option awards granted under our 2024 POP that are early exercisable only upon satisfaction of the Performance Condition.

(6) Consists of (i) 4,037 shares of common stock held of record by Dr. Drappa and (ii) 532,638 shares of common stock subject to options that are exercisable within 60 days of March 1, 2026. Includes 70,802 shares of common stock subject to option awards granted under our 2024 POP that are early exercisable only upon satisfaction of the Performance Condition.

(7) Consists of (i) 18,404 shares of common stock held by The Colowick Trust, for which Dr. Colowick serves as trustee, and (ii) the shares of common stock described in footnote (1) above, over which Dr. Colowick may be deemed to hold voting and dispositive power.

(8) Consists of (i) 7,064 shares of common stock held of record by Patrick Machado Revocable Trust, for which Mr. Machado serves as trustee, and (ii) 143,051 shares of common stock subject to options that are exercisable within 60 days of March 1, 2026.

(9) Consists of 39,572 shares of common stock subject to options that are exercisable within 60 days of March 1, 2026.

(10) Consists of 64,331 shares of common stock subject to options that are exercisable within 60 days of March 1, 2026.

(11) Consists of (i) 23,529 shares of common stock held of record by Dr. Yao and (ii) 14,617 shares of common stock subject to options that are exercisable within 60 days of March 1, 2026.

(12) Consists of (i) 38,308,871 shares of common stock beneficially owned by our current executive officers and directors and (ii) 5,542,614 shares of common stock subject to options that are exercisable within 60 days of March 1, 2026. Includes 1,172,520 shares of common stock subject to option awards granted under our 2024 POP that are early exercisable only upon satisfaction of the Performance Condition.

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

Certain Related Party Transactions

The following includes a summary of transactions since January 1, 2024 and any currently proposed transactions to which we have been or are to be a party in which the amount involved exceeded or will exceed the lesser of $120,000 and 1% of our total assets, and in which any of our directors, executive officers or, to our knowledge, beneficial owners of more than 5% of our capital stock or any member of the immediate family of any of the foregoing persons had or will have a direct or indirect material interest, other than equity and other compensation, termination, change in control and other arrangements, which are described under Item 11, Executive Compensation. We also describe below certain other transactions with our directors, executive officers and stockholders.

2026 Public Offering

On January 7, 2026, we entered into the Underwriting Agreement with the Underwriters, relating to the issuance and sale in a public offering of 17,650,000 shares of the Company's common stock at a price of $17.00 per share. Certain entities affiliated with Foresite Capital Management and Samsara BioCapital, LP participated in the public offering on the same terms and conditions as all other purchasers, purchasing 411,764 and 588,235 shares, for a purchase price of $6,999,988 and $9,999,995, respectively.

Voting and Support Agreements

Concurrently with the execution of the Merger Agreement, certain entities affiliated with Foresite Capital Management, certain entities affiliated with AyurMaya Capital Management Fund, LP, Samsara BioCapital, LP, and Martin Babler, who collectively held approximately 62% of the outstanding capital stock as of such date, entered into voting and support agreements, providing among other things, that such stockholders would vote all of their shares of capital stock in favor of adopting the Merger Agreement and approving the issuance of shares of our common stock to ACELYRIN stockholders in connection with the Merger.

Foresite Labs Services Agreement

In January 2021, we entered into a services agreement with Foresite Labs, LLC ("Foresite Labs"), an entity affiliated with Foresite Capital Management, a holder of more than 5% of our outstanding capital stock, which was amended on August 24, 2021 and further amended on December 22, 2023, and expires in December 2026, unless terminated earlier by the parties, pursuant to which Foresite Labs provides us with data and analytics services and other scientific support. Foresite Labs invoices us for the services quarterly in advance based on a mutually agreed service fee estimate, which is reconciled at the end of each quarter. For the year ended December 31, 2025, we recognized $1.1 million as research and development expenses under the service agreement. Accrued expenses under the service agreement were zero as of December 31, 2025.

Series C and Series C-1 Convertible Preferred Stock Financing

In March and May 2024, we issued and sold an aggregate of 82,529,783 shares of Series C redeemable convertible preferred stock at a purchase price of $3.13826 per share. The aggregate proceeds for the Series C redeemable convertible preferred shares were $258,999,917.04.

The following table summarizes the Series C and Series C-1 convertible preferred stock purchased by holders of more than 5% of our capital stock and entities affiliated with our executive officers and members of the Board.

Participants[1]	Shares of Series C Redeemable Convertible Preferred Stock (#)	Shares of Series C-1 Redeemable Convertible Preferred Stock (#)	Aggregate Proceeds ($)
AyurMaya Capital Management Fund, LP[2]	12,745,916	—	39,999,998.36
Entities affiliated with Baker Brothers Life Sciences, L.P.[3]	8,252,980	—	25,899,997.04
Entities affiliated with Foresite Capital Management[4]	19,118,870	—	59,999,985.00
Samsara BioCapital, LP[5]	7,966,196	—	24,999,994.26
venBio Global Strategic Fund IV, L.P.[6]	9,559,436	—	29,999,995.64

(1) Additional details regarding these stockholders and their equity holdings are included under Item 12 of this report in the subsection titled "Security Ownership of Certain Beneficial Owners and Management."

(2) Alan Colowick, M.D., M.P.H., a member of the Board, is Managing Director of Matrix Capital Management Company, an affiliate of AyurMaya Capital Management Fund LP, a holder of greater than 5% of our capital stock. Immediately prior to the closing of our IPO, all shares of our Series C redeemable convertible preferred stock held by AyurMaya Capital Management Fund, LP converted into 2,726,398 shares of our common stock.

(3) Consists of (i) 7,573,328 shares of our Series C redeemable convertible preferred stock issued to Baker Brothers Life Sciences, L.P. ("BBA") and (ii) 679,652 shares of our Series C redeemable convertible preferred stock issued to 667, L.P (together with BBA, the "BBA Funds"). Immediately prior to the closing of our IPO, all shares of our Series C redeemable convertible preferred stock held by entities affiliated with BBA converted into 1,765,342 shares of our non-voting common stock.

(4) Consists of (i) 4,779,718 shares of our Series C redeemable convertible preferred stock issued to Foresite Capital Fund V, L.P., (ii) 3,186,478 shares of our Series C redeemable convertible preferred stock issued to Foresite Capital Opportunity Fund V, L.P., (iii) 3,186,478 shares of our Series C redeemable convertible preferred stock issued to Foresite Labs Fund I, L.P., and (iv) 7,966,196 shares of our Series C redeemable convertible preferred stock issued to Foresite Capital Fund VI, L.P. Entities affiliated with Foresite Capital Management beneficially own more than 5% of our outstanding capital stock. James B. Tananbaum, M.D., a member of the Board, is President, Chief Executive Officer and a director of Foresite Capital Management. Immediately prior to the closing of our IPO, all shares of our Series C redeemable convertible preferred stock held by entities affiliated with Foresite Capital Management converted into 4,089,592 shares of our common stock.

(5) Srinivas Akkaraju, M.D., Ph.D., a member of the Board, is the managing member of Samsara BioCapital, LP. Immediately prior to the closing of our IPO, all shares of our Series C redeemable convertible preferred stock held by Samsara BioCapital, LP converted into 1,703,998 shares of our common stock.

(6) Richard Gaster, M.D., Ph.D., a former member of the Board who resigned from the Board in June 2024, is a managing partner of venBio Partners LLC. Immediately prior to the closing of our IPO, all shares of our Series C redeemable convertible preferred stock held by venBio Global Strategic Fund IV, L.P. converted into 2,044,798 shares of our common stock.

Concurrent Private Placement

In July 2024, we sold an aggregate of 13,125,000 shares of our common stock at a price to the public of $16.00 per share in our IPO. In connection with our IPO, AyurMaya Capital Management Fund, LP ("AyurMaya"), an existing holder of more than 5% of our capital stock, which is affiliated with one of our directors, agreed to purchase $40.0 million in shares of our common stock at the IPO price per share, in a private placement transaction (the "Concurrent Private Placement"). The sale of shares of our common stock in the Concurrent Private Placement to AyurMaya was not registered under the Securities Act, and as such, the shares may not be offered or sold absent registration or an applicable exemption from registration.

Investors' Rights Agreement

We are party to an amended and restated investors' rights agreement with, among others, holders of more than 5% of our capital stock and entities with which certain of our directors are affiliated. Certain of the holders of our common stock are entitled to rights with respect to the registration of their shares under the Securities Act, subject to certain exceptions. The investors' rights agreement also provided for a right of first refusal in favor of certain holders of redeemable convertible

preferred stock with regard to certain issuances of our capital stock. The right of first refusal terminated upon the consummation of our IPO.

Employment Agreements and Stock Option Grants to Directors and Executive Officers

We have entered into employment agreements with certain of our named executive officers and granted stock options to our named executive officers and certain of our directors, as more fully described in under Item 11, Executive Compensation.

Limitations on Liability and Indemnification Agreements

Our amended and restated certificate of incorporation contains provisions limiting the liability of directors, and our amended and restated bylaws provides that we will indemnify each of our directors and officers to the fullest extent permitted under Delaware law. Our amended and restated certificate of incorporation and amended and restated bylaws also provide the Board with discretion to indemnify our employees and other agents when determined appropriate by the Board. In addition, we have entered into an indemnification agreement with each of our directors and executive officers, which will require us to indemnify them. These agreements provide, among other things, that we will indemnify our executive officer or director, under the circumstances and to the extent provided for in the indemnification agreement, 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 a director, officer or other agent of us, and otherwise to the fullest extent permitted under Delaware law and our amended and restated bylaws.

Related Person Transactions Policy and Procedures

We have adopted a written policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our common stock and any members of the immediate family of any of the foregoing persons are not permitted to enter into a related person transaction with us without the approval or ratification of our Audit Committee (or, where Audit Committee approval would be inappropriate, to another independent body of the Board). Any request for us to enter into a transaction with an executive officer, director, nominee for election as a director, beneficial owner of more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, in which the amount involved exceeds $120,000 (or, if less, 1% of the average of our total assets in a fiscal year) and such person would have a direct or indirect interest, must be presented to our Audit Committee for review, consideration and approval or ratification.

Under the policy, where a transaction has been identified as a related person transaction, management must present information regarding the proposed related person transaction to our Audit Committee (or, where Audit Committee approval would be inappropriate, to another independent body of the Board) for consideration and approval or ratification. The presentation must include a description of, among other things, the material facts (including the proposed aggregate value), the interests, direct and indirect, of the related persons, the benefits to us of the transaction, the availability of other sources of comparable products or services, an assessment of whether the proposed related person transaction is on terms that are comparable to the terms available to or from, as the case maybe, an unrelated third party, and management's recommendation.

To identify related person transactions in advance, we rely on information supplied by our executive officers, directors and certain significant stockholders. In approving or rejecting any proposed related person transaction, our Audit Committee considers all relevant available facts and circumstances, including, but not limited to (a) whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, (b) the risks, costs and benefits to us, (c) the extent of the related person's interest in the transaction, including, without limitation, the impact on a director's independence in the event the related person is a director, immediate family member of a director or an entity with which a director is affiliated, and (d) the availability of other sources for comparable services or products. In the event a director has an interest in the proposed transaction, the director must recuse himself or herself from the deliberations and approval or ratification. The policy requires that, in determining whether to approve, ratify or reject a related person transaction, our Audit Committee approves only those related person transactions that, in light of known circumstances, are in, or are not inconsistent with, our best interests and the best

interests of our stockholders, as the Audit Committee determines in the good faith exercise of its discretion.

Director Independence

Under the Nasdaq Listing Rules, independent directors must comprise a majority of a listed company's board of directors within one year of the listing date. In addition, Nasdaq requires that, subject to specified exceptions, each member of a listed company's audit, compensation and nominating and corporate governance committees be independent and that audit committee members also satisfy independence criteria set forth in Rule 10A-3 under the Exchange Act. Under Rule 5605(a)(2), a director will only qualify as an "independent director" if, in the opinion of the Board, that person does not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In order to be considered independent for purposes of Rule 10A-3, a member of an audit committee of a listed company may not, other than in his or her capacity as a member of the audit committee, the board of directors, or any other board committee, accept, directly or indirectly, any consulting, advisory, or other compensatory fee from the listed company or any of its subsidiaries or otherwise be an affiliated person of the listed company or any of its subsidiaries.

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 us, our senior management or our independent auditors, and all other facts and circumstances the Board deemed relevant including the beneficial ownership of our common stock, the Board has affirmatively determined that none of our directors, other than Martin Babler, has any relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director, and that each of these directors is "independent" as that term is defined under the Nasdaq Listing Rules. Our Board has determined that Martin Babler is not an independent director by virtue of his service as our Chief Executive Officer. Accordingly, a majority of our directors are independent as required under applicable Nasdaq Listing Rules. In addition, the Board has determined that each member of the Audit Committee, Compensation Committee and Nominating and Corporate Governance Committee meets the applicable Nasdaq and SEC rules and regulations regarding "independence" and that each member is free of any relationship that would impair his or her individual exercise of independent judgment with regard to the company.

Item 14. Principal Accountant Fees and Services

Independent Registered Public Accounting Firm Fees and Services

In connection with the audit of our 2025 financial statements, we entered into an engagement agreement with PricewaterhouseCoopers LLP, which sets forth the terms under which PricewaterhouseCoopers LLP performed audit services for the Company.

The following table represents aggregate fees billed to us for the fiscal years ended December 31, 2025 and December 31, 2024 by PricewaterhouseCoopers LLP, our independent registered public accounting firm (in thousands).

	Fiscal Year Ended December 31,	
	2025	2024
Audit Fees[(1)]	$ 2,110	$ 1,691
Audit-Related Fees	121	—
Tax Fees	—	—
All Other Fees[(2)]	2	2
Total Fees	$ 2,233	$ 1,693

(1) "Audit Fees" consist of fees in connection with the audit of our annual consolidated financial statements, including the audited consolidated financial statements as well as other financial statements presented in the audited consolidated financial statements presented in this Annual Report on Form 10-K and services that are normally provided by our independent registered public accounting firm in connection with regulatory filings or engagements for those fiscal years. Included in the fiscal year 2024 Audit Fees are fees billed in connection with our IPO.

(2) "All Other Fees" consist of subscription fees to the online library of disclosure checklists and accounting research literature.

All fees described above were pre-approved by our Audit Committee.

Pre-Approval Policies and Procedures

The Audit Committee must pre-approve the audit and non-audit services rendered by our independent registered public accounting firm. 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. Pursuant to the policy, the Audit Committee delegated specific pre-approval authority to the chairperson of the Audit Committee, concurrent with the Audit Committee's authority, to approve any one or more individual permitted non-audit services for which estimated fees do not exceed $100,000 as well as adjustments to any estimated pre-approval fee thresholds up to $50,000 for any individual service, but the chairperson's exercise of such authority must be reported to the full Audit Committee at its next scheduled meeting.

The Audit Committee has determined that the rendering of services other than audit services by PricewaterhouseCoopers LLP is compatible with maintaining the principal accountant's independence.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a)

(1) Financial Statements – See the "*Index to Consolidated Financial Statements* included in Part II, Item 8 of this Annual Report on Form 10-K for a list of the financial statements filed as part of this report.

(2) Financial Statement Schedules – All financial statement schedules have been omitted because the information required to be presented in them is not applicable or is shown in the consolidated financial statements or related notes, included in this Annual Report on Form 10-K.

b) Exhibits

Exhibit Number		Description
2.1		Agreement and Plan of Merger, by and among the Registrant, ACELYRIN, Inc. and Arrow Merger Sub, Inc. dated as of February 6, 2025 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 6, 2025).
2.2		Amendment to the Agreement and Plan of Merger, dated as of April 20, 2025 (incorporated by reference to Exhibit 2.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on April 21, 2025).
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, filed with the SEC on July 1, 2024)
3.2		Amended and Restated Bylaws of the Registrant (incorporated by reference to Exhibit 3.2 to the Registrant's Current Report on Form 8-K, filed with the SEC on July 1, 2024)
4.1		Description of Capital Stock (incorporated by reference to the Registrant's Registration Statement on Form 8-A (File No. 001-42143) filed with the SEC on June 25, 2024)
4.2		Amended and Restated Investors' Rights Agreement, by and among the Registrant and certain of its stockholders, dated March 4, 2024 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form S-1 (file No. 333-280068), filed with the SEC on June 7, 2024)
4.3		Description of Capital Stock (incorporated by reference to Exhibit 4.3 to the Registrant's Annual Report on Form 10-K (File No. 001-42143) for the period ended December 31, 2024, filed with the SEC on March 19, 2025, as amended on April 23, 2025)
10.1		Alumis Inc. 2021 Stock Plan, as amended (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.2		Forms of Stock Option Grant Notice under Alumis Inc. 2021 Stock Plan, as amended (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.3		Alumis Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on File Form S-1/A (File No. 333-280068), filed with the SEC on June 24, 2024)
10.4		Forms of Stock Option Grant Notice, Stock Option Agreement and Notice of Exercise under the Alumis Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form S-1/A (File No. 333-280068), filed with the SEC on June 24, 2024)
10.5		Forms of Restricted Stock Unit Grant Notice and Award Agreement under the Alumis Inc. 2024 Equity Incentive Plan (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form S-1/A (File No. 333-280068), filed with the SEC on June 24, 2024)

10.6		Alumis Inc. 2024 Performance Option Plan (incorporated by reference to Exhibit 10.6 to the Registrant's Registration Statement on Form S-1/A (File No. 333-280068), filed with the SEC on June 24, 2024)
10.7		Forms of Stock Option Grant Notice, Stock Options Agreement and Notice of Exercise under the Alumis Inc. 2024 Performance Option Plan (incorporated by reference to Exhibit 10.7 to the Registrant's Registration Statement on Form S-1/A (File No. 333-280068), filed with the SEC on June 24, 2024)
10.8		Alumis Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.8 to the Registrant's Registration Statement on Form S-1/A (File No. 333-280068), filed with the SEC on June 24, 2024)
10.9		Alumis Inc. Amended and Restated Non-Employee Director Compensation Policy (incorporated by reference to Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2025, filed with the SEC on November 13, 2025
10.10		Form of Indemnification Agreement by and between Registrant and its directors and executive officers. (incorporated by reference to Exhibit 10.10 to the Registrant's Registration Statement on Form S-1/A (File No. 333-280068), filed with the SEC on June 24, 2024)
10.11		Lease Agreement, dated as of August 11, 2022, by and between the Registrant and PG VII 280 East Grand, LLC (incorporated by reference to Exhibit 10.12 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.12		Offer Letter, dated as of September 15, 2021, by and between the Registrant and Martin Babler (incorporated by reference to Exhibit 10.13 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.13		Offer Letter, dated as of September 15, 2021, by and between the Registrant and David Goldstein (incorporated by reference to Exhibit 10.14 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.14		Offer Letter, dated as of September 15, 2021, by and between the Registrant and Roy Hardiman (incorporated by reference to Exhibit 10.15 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.15		Offer Letter, dated as of March 15, 2021, by and between the Registrant and Mark Bradley (incorporated by reference to Exhibit 10.16 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.16		Amendment to Offer Letter, dated as of July 18, 2023, by and between the Registrant and Mark Bradley (incorporated by reference to Exhibit 10.17 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.17		Offer Letter, dated as of November 12, 2021, by and between the Registrant and Derrick Richardson (incorporated by reference to Exhibit 10.18 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.18		Offer Letter, dated as of January 12, 2022, by and between the Registrant and Sara Klein (incorporated by reference to Exhibit 10.19 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.19		Offer Letter, dated as of March 22, 2022, by and between the Registrant and John Schroer (incorporated by reference to Exhibit 10.20 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.20		Offer Letter, dated as of June 24, 2022, by and between the Registrant and Jörn Drappa (incorporated by reference to Exhibit 10.21 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.21*		Offer Letter, dated as of September 6, 2024, by and between the Registrant and Sanam Pangali

10.22		Stock Purchase Agreement, dated as of March 5, 2021, by and among the Registrant, FronThera International Group Limited and FronThera U.S. Holdings, Inc. (incorporated by reference to Exhibit 10.22 to the Registrant's Registration Statement on Form S-1 (File No. 333-280068), filed with the SEC on June 7, 2024)
10.23		Alumis Inc. Severance and Change in Control Plan (incorporated by reference to Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed with the SEC on February 21, 2025)
10.24*		Controlled Equity Offering[SM] Sales Agreement, dated March 18, 2026, by and between the Registrant and Cantor Fitzgerald & Co.
19.1		Alumis Inc. Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Registrant's Annual Report on Form 10-K (File No. 001-42143) for the period ended December 31, 2024, filed with the SEC on March 19, 2025, as amended on April 23, 2025)
21.1*		List of subsidiaries of Alumis Inc.
23.1*		Consent of PricewaterhouseCoopers LLP, independent registered public accounting firm of Alumis Inc.
24.1*		Power of Attorney (included on signature page)
31.1*		Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*		Certification of Principal Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as amended, as adopted pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*#		Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*#		Certification of Chief Financial Officer Pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
97.1		Alumis Inc. Incentive Compensation Recoupment Policy (incorporated by reference to Exhibit 97.1 to the Registrant's Annual Report on Form 10-K (File No. 001-42143) for the period ended December 31, 2024, filed with the SEC on March 19, 2025, as amended on April 23, 2025)
101.INS*		Inline 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 accompanies the Annual Report on Form 10-K pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 and shall not be deemed to be "filed" by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

Item 16. Form 10-K Summary

None.

SIGNATURES

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

Date: March 19, 2026

ALUMIS INC.

By: /s/ Martin Babler
Name: Martin Babler
Title: President and Chief Executive Officer
(Principal Executive Officer)

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Martin Babler and John Schroer his or her true and lawful attorney-in-fact and agent, with full power of substitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent, or his or her substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below on March 19, 2026, by the following persons on behalf of the registrant and in the capacities indicated:

Signature	Title
/s/ Martin Babler Martin Babler	President and Chief Executive Officer and Director (*Principal Executive Officer)*
/s/ John Schroer John Schroer	Chief Financial Officer *(Principal Financial and Accounting Officer)*
/s/ Srinivas Akkaraju, M.D., Ph.D. Srinivas Akkaraju, M.D., Ph.D.	Director
/s/ Alan B. Colowick, M.D., M.P.H. Alan B. Colowick M.D., M.P.H.	Director
/s/ Patrick Machado Patrick Machado, J.D.	Director
/s/ Sapna Srivastava, Ph.D. Sapna Srivastava, Ph.D.	Director
/s/ James B. Tananbaum, M.D. James B. Tananbaum, M.D.	Director
/s/ Lynn Tetrault, J.D. Lynn Tetrault, J.D.	Director
/s/ Zhengbin Yao, Ph.D. Zhengbin Yao, Ph.D.	Director