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: 001-40551

Acumen Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**36-4108129**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
1210-1220 Washington St., Suite 210	
Newton, Massachusetts	**02465**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (617) 344-4190

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	ABOS	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. ☐ Yes ☒ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the 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 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 Act). ☐ Yes ☒ No

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant as of June 30, 2025, the last business day of the registrant's second fiscal quarter, was $45.3 million.

The number of the registrant's shares of common stock outstanding as of March 20, 2026 was 72,212,758.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement relating to its 2026 annual meeting of the shareholders, or the 2026 Proxy Statement, are incorporated by reference into Part III of this Annual Report on Form 10-K where indicated. The 2026 Proxy Statement will be filed with the U.S. Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, about us and our industry 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 results of operations or 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 because they contain words such as “anticipate,” “believe,” “contemplate,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will” or “would” or the negative of these words or other similar terms or expressions. These forward-looking statements include, but are not limited to, statements concerning the following:

- the sufficiency of our existing cash and cash equivalents and marketable securities to fund our future operating expenses and capital expenditure requirements;
- our ability to obtain funding for our operations, including funding necessary to develop and commercialize sabirnetug or any Aß oligomer-targeted Enhanced Brain Delivery, or EBD™, product candidates that we may develop pursuant to our collaboration with JCR Pharmaceuticals Co. Ltd., or JCR, subject to obtaining necessary regulatory approvals, and our ability to continue as a going concern;
- the ability of our clinical trials to demonstrate the safety and efficacy of sabirnetug, and other positive results;
- the therapeutic potential of sabirnetug, including its potential for improved safety and efficacy as compared to other monoclonal antibodies approved and or in development, as well as our expectations concerning our ongoing ALTITUDE-AD clinical trial and any future clinical trials we may conduct;
- the structure, focus, success, cost and timing of our development activities, nonclinical studies and clinical trials, and the reporting of data from those clinical trials;
- our plans relating to commercializing sabirnetug or any other product candidate that we may advance into clinical trials, subject to obtaining necessary regulatory approvals;
- our ability to attract and retain key scientific and clinical personnel;
- our ability to contract with third-party suppliers and manufacturers and their ability to perform adequately;
- our reliance on third parties to conduct both preclinical trials related to the potential development of an Aß oligomer-targeted EBD™ therapy and clinical trials of sabirnetug, as well as any other product candidate we may develop, and to manufacture sabirnetug and any other product candidates we may develop for nonclinical studies and clinical trials;
- the success of competing therapies that are or may become available;
- our plans and ability to obtain or protect our intellectual property rights, including extensions of existing patent terms where available or the use of data market exclusivity to provide protection from generic or biosimilar versions of our product;
- the scope of protection we are able to establish and maintain for intellectual property rights covering sabirnetug, any other product candidates we may develop, and our technology;
- potential claims relating to our intellectual property;
- existing regulations and regulatory developments in the United States and other jurisdictions;
- our ability to obtain and maintain regulatory approval of sabirnetug, and any related restrictions, limitations and/or warnings in the label of any approved product candidate;
- our plans relating to the further development and manufacturing of sabirnetug and any other product candidates we may develop, including additional therapeutic indications we may pursue;
- our ability to develop and maintain our corporate infrastructure, including our ability to design and maintain an effective system of internal controls;
- our financial performance; and
- our expectations regarding the time period during which we will be an emerging growth company under the Jumpstart Our Business Startups Act of 2012, or the JOBS Act.

You should not rely on forward-looking statements as predictions of future events. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described under the header “Risk Factors” and elsewhere in this Annual Report on Form 10-K. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained herein. The results, events and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this Annual Report on Form 10-K relate only to events as of the date on which the statements are made, and we undertake no obligation to update them to reflect events or circumstances after the date of this Annual Report on Form 10-K or to reflect new information or the occurrence of unanticipated events, except as required by law.

Unless the context otherwise indicates, references in this report to the terms “Acumen,” “the Company,” “we,” “our” and “us” refer to Acumen Pharmaceuticals, Inc.

We may announce material business and financial information to our investors using our investor relations website (investors.acumenpharm.com). We therefore encourage investors and others interested in Acumen to review the information that we make available on our website, in addition to following our filings with the Securities and Exchange Commission, or SEC, webcasts, press releases and conference calls. Our website and information included in or linked to our website are not part of this Annual Report on Form 10-K.

RISK FACTORS SUMMARY

Our business is subject to a number of risks of which you should be aware before making a decision to invest in our common stock. These risks are more fully described in "Part I, Item 1A. Risk Factors" of this Annual Report on Form 10-K, including the following:

- We are a clinical-stage biopharmaceutical company with a limited operating history.
- We have no product candidates approved for commercial sale, we have never generated any revenue from product sales and we may never be profitable.
- We will require substantial additional funding to finance our operations, complete the development and commercialization of sabirnetug for Alzheimer's disease, or AD, and evaluate future product candidates, including any Aß oligomer-targeted EBD™ product candidates that we may develop pursuant to our collaboration with JCR. If we are unable to raise this funding when needed, we may be forced to delay, reduce or eliminate our drug development programs or other operations.
- Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report in our audited financial statements included in this Annual Report on Form 10-K. If we are unable to obtain sufficient funding, our business, results of operations, financial condition and prospects may be adversely affected and we may be unable to continue as a going concern.
- We are substantially dependent on the success of sabirnetug, our sole product candidate, which will require significant clinical testing before we can seek regulatory approval and potentially launch commercial sales, and which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized, even if approved.
- We have concentrated our research and development efforts on the treatment of AD, a field that has to date seen very limited success in drug development.
- Our approach to the potential treatment of AD is based on a novel therapeutic approach, which exposes us to unforeseen risks.
- Nonclinical and clinical drug development involves a lengthy, expensive and uncertain process. The results of nonclinical studies and early clinical trials are not always predictive of future results. Sabirnetug or any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.
- Clinical failure can occur at any stage of clinical development, and we have never submitted a biologics license application or other marketing authorization application.
- We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.
- If we are unable to enter into a commercial collaboration or, alternatively, establish internal sales, marketing and distribution capabilities for sabirnetug or any other product candidate, including any Aß oligomer-targeted EBD product candidates that we may develop pursuant to our collaboration with JCR, that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.
- We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more effective than ours.
- We currently rely on contract manufacturing organizations, or CMOs, to supply components of and manufacture sabirnetug. The loss of any of these CMOs or the failure of any of them to meet their obligations to us could affect our ability to develop sabirnetug in a timely manner.
- We intend to rely on contract research organizations and other third parties to conduct, supervise and monitor a significant portion of our research and nonclinical testing and clinical trials for sabirnetug and any future product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

- If we are unable to obtain and maintain sufficient intellectual property protection for sabirnetug and any future product candidate, including any Aß oligomer-targeted EBD™ product candidates, as well as any other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidate, and other proprietary technologies if approved, may be adversely affected.

PART I

Item 1. Business.

Overview

We are a clinical-stage biopharmaceutical company developing a novel disease-modifying approach targeting what we believe to be a key underlying cause of Alzheimer's disease, or AD. Alzheimer's disease is a progressive neurodegenerative disease of the brain that leads to loss of memory and cognitive functions and ultimately results in death. Alzheimer's disease is currently estimated to affect approximately seven million people in the United States and approximately 55 million people worldwide and was the sixth-leading cause of death among individuals aged 65 and older in 2022 in the United States. Due to the aging population, patient populations in the United States impacted by AD are expected to grow to approximately 13 million people by 2050 without effective preventative measures or safe and effective disease-modifying treatments. By 2050, healthcare costs for AD in the United States alone are estimated to near $1 trillion.

Our scientific founders pioneered research on soluble amyloid-beta oligomers, or AßOs, which are globular assemblies of the amyloid-beta, or Aß, peptide that are distinct from Aß monomers and amyloid plaques. Based on decades of research and supporting evidence, AßOs have gained increasing scientific acceptance as a primary toxin involved in the initiation and propagation of AD pathology. We are currently focused on advancing a targeted immunotherapy drug candidate, sabirnetug (ACU193), in our Phase 2 ALTITUDE-AD clinical trial, and expect to announce top-line results in late 2026. Sabirnetug is a recombinant humanized immunoglobulin gamma 2, or IgG2, monoclonal antibody, or mAb, that was designed to selectively target AßOs, has demonstrated functional and protective effects in in vitro assays, and has demonstrated in vivo safety and pharmacologic activity in multiple animal species, including transgenic mouse models for AD, as well as in human AD patients in our Phase 1 INTERCEPT-AD clinical trial of sabirnetug, the results of which were announced in July 2023. ALTITUDE-AD is a randomized, double-blind, placebo-controlled, three-arm clinical trial designed to evaluate the clinical efficacy, safety and tolerability of sabirnetug with up to 180 participants per arm for a total of 542 participants with mild cognitive impairment, or MCI, or mild dementia due to AD. We plan to use the Integrated Alzheimer's Disease Rating Scale at 18 months as the primary outcome measure. The active doses for ALTITUDE-AD are 35 mg/kg and 50 mg/kg, dosed intravenously every four weeks. These dose levels and frequency were selected based on extensive pharmacokinetic, or PK, and pharmacodynamic, or PD, modeling from our Phase 1 INTERCEPT-AD clinical trial of sabirnetug.

We completed our Phase 1 INTERCEPT-AD clinical trial of sabirnetug in the second quarter of 2023. This trial enrolled 65 participants with early AD, and 62 participants received at least one dose of study drug. INTERCEPT-AD was a U.S.-based, multi-center, randomized, double-blind, placebo-controlled clinical trial with overlapping single ascending dose, or SAD, and multiple ascending dose, or MAD, cohorts evaluating patients with early AD. The overall objective of the trial was to evaluate the safety and tolerability of sabirnetug administered intravenously, or IV, and to establish clinical proof of mechanism of sabirnetug. The primary trial endpoints were focused on safety and immunogenicity. An important safety measure was the use of magnetic resonance imaging, or MRI, to assess the presence or absence of amyloid-related imaging abnormalities, or ARIA. Secondary endpoints included pharmacokinetics in plasma and CSF and target engagement as evidenced by detection of sabirnetug bound to AßOs in CSF. Clinical scales typically used in AD trials as well as computerized cognitive testing and arterial spin labeling, or ASL, with MRI scans (which can be used to assess cerebral blood flow) were included as exploratory measures.

INTERCEPT-AD demonstrated that sabirnetug met the primary and secondary objectives of this clinical trial in 62 participants with early AD. Sabirnetug was well-tolerated throughout the SAD and MAD dose cohorts, with an overall rate of ARIA-E of 10.4%. The incidence of ARIA-E was dose dependent, with a rate of 7% for patients given 10 mg/kg or 25 mg/kg and 21% for patients given 60 mg/kg. An analysis of change in amyloid plaque load, as measured by positron emission tomography, or PET, Centiloids demonstrated a rapid, dose-related mean decrease at the higher dose levels studied. Statistically significant, dose-related central target engagement was observed as measured by sabirnetug-AßO complex, establishing the first target engagement assay developed that is specific to an AßO-targeting antibody. This assay also demonstrated near maximal target engagement for patients receiving 25 mg/kg every two weeks, or Q2W, or 60 mg/kg every four weeks, or Q4W. A number of downstream biomarkers in CSF specific to amyloid and tau pathology and synaptic injury showed improvement in the MAD cohorts, further supporting a drug effect of sabirnetug on Alzheimer's pathology. These included effects of sabirnetug on p-tau181, which reflects damage to neurons and is known to be elevated in CSF of patients with AD, and effects of sabirnetug on neurogranin and vesicle-associated membrane protein 2, or VAMP2, which reflect damage to neuronal synapsis and are elevated in CSF of patients with AD.

In addition, we are investigating a blood-brain barrier-penetrating, Aß oligomer-targeted Enhanced Brain Delivery (EBD™) therapy for the treatment of AD. In March 2026, we announced certain preclinical data from EBD candidates, including *in vitro*, *in vivo* and non-human primate study results, supporting the advancement of the EBD program: (1) EBD candidates achieved 14-40x higher brain levels in non-human primates compared to native antibodies 24 hours after dosing; (2) hematology data in non-human primates indicated low potential for anemia, including that, at 24 hours after subcutaneous dosing, EBD candidates demonstrated no observed change in red blood cell count, hematocrit, hemoglobin or reticulocyte count; and (3) favorable stability profile and enhanced brain delivery support a path to subcutaneous administration with low-volume devices. Based on this data, an IND is targeted for mid-2027. In July 2025, we entered into a collaboration, option and license agreement with JCR Pharmaceuticals Co. Ltd., or JCR, to develop an Aß oligomer-targeted EBD™ therapy for AD. Under the terms of the agreement, in addition to an upfront license payment that we paid to JCR, if we exercise our exclusive option to develop up to two development candidates, JCR will be eligible for an option exercise payment of $9.25 million. Our option is expected to be exercised when we have selected or identified up to two preclinical candidates we would license and advance into IND-enabling activities. JCR will also be eligible to receive future milestone payments of up to $40.0 million related to development, and up to $515.0 million related to sales, for a total of up to $555.0 million, as well as single-digit percentage royalties on sales of any products that emerge from the collaboration. The combination of sabirnetug or additional, novel, AβO-selective antibodies with JCR's blood-brain barrier-penetrating technology, J-Brain Cargo®, strengthens Acumen's portfolio of AβO-targeted therapies. The partnership is designed to advance potential next-generation treatment options for people living with AD, by targeting the development of products with enhanced efficacy, safety and convenience.

In November 2023, we announced a global collaboration and license agreement with Halozyme, Inc., or Halozyme, to develop a subcutaneous formulation of sabirnetug. We announced the results of a Phase 1 clinical trial investigating a subcutaneous dosing option of sabirnetug in March 2025. This study in healthy volunteers enrolled 16 subjects who received four weekly subcutaneous doses of 1,200 mg of sabirnetug and 12 subjects who received single IV doses of 2,800 mg of sabirnetug. The most frequently reported adverse events included injection site reactions (62.5%), all of which were mild (Grade 1) in severity and resolved. No other safety issues were identified. Additionally, subcutaneous administration of sabirnetug was shown to produce sufficient systemic exposure to support further development of this formulation as a more convenient administration option for patients.

Understanding the Foundation of Our Therapeutic Approach

While the pathology of AD was first described by Dr. Alois Alzheimer in 1906, the amyloid hypothesis was not developed until the Aß peptide was first identified as a major constituent of amyloid plaques in the 1980s. The primary constituent of amyloid plaques is the Aß peptide, although other proteins are present to lesser degrees. Historically, the primary hypothesis of decades of AD research, known as the amyloid hypothesis, held that AD dementia is the clinical consequence of Aß peptide monomers accumulating into extracellular amyloid plaques, which in turn contribute to the formation of intracellular neurofibrillary tangles composed of the tau protein, which is directly linked to neuronal cell death. Additionally, amyloid plaques cause inflammation. The disruption of synaptic function, inflammation and brain cell loss ultimately lead to progressive Alzheimer's related dementia.

The amyloid hypothesis was more firmly established when a series of genetic mutations causing AD were discovered in the early to mid-1990s. These mutations were found in genes coding for the Amyloid Precursor Protein, or APP, and the genes coding for one of the enzymes which cleaves APP, creating the Aß peptide. Based on this hypothesis, a number of mAbs currently or previously in clinical development for AD have primarily targeted either Aß monomers or amyloid plaques; for our purposes, this broadly defined class is referred to as anti-Aß/plaque antibodies. One of these antibodies, lecanemab, or LEQEMBI®, which was developed to target soluble aggregated species of Aß known as protofibrils, received approval from the U.S. Food and Drug Administration, or the FDA, in 2023. Another antibody, donanemab, which was developed to target amyloid plaques, was approved by the FDA in 2024. The clinical data available to date, even for these approved mAbs, indicate some of the potential limitations of these approaches with respect to clinically meaningful patient benefit and safety.

Though alternative hypotheses to the amyloid hypothesis have been proposed, e.g., that neurodegeneration is a consequence of another process such as infection, the field has now developed an understanding that three predominant pools of Aß species exist in vivo: Aß monomers (single Aß peptides), amyloid plaques (insoluble fibrillar Aß), and soluble AßOs (dimers up to 200-mers). Some experts in the field differentiate soluble AßO oligomers into globular structures or linear protofibrils. Linear soluble Aß protofibrils may elongate to form the insoluble fibrils that make up deposited amyloid plaques. Sabirnetug was developed to bind to globular AßOs rather than to Aß monomers, fibrils or deposited amyloid

plaques. The more recent recognition of the direct toxicity of soluble AßOs to neurons is the central tenet of our therapeutic approach.

AßOs have been observed to be potent neurotoxins that cause both acute synaptic toxicity and induce neurodegeneration. Experimentally in animal models, the accumulation of AßOs is associated with core AD neuropathology, including synapse deterioration and loss, tau hyper-phosphorylation and inflammation. Research has also shown that the accumulation of AßOs is associated with AD-related behavioral deficits, such as learning and memory impairment. In light of this evidence, we believe that blocking the toxicity of AßOs is a differentiated and promising approach for maximizing the therapeutic index (efficacy compared to safety) for the treatment of AD.

Our Product Candidate

Our product candidate, sabirnetug, is a recombinant humanized, affinity-matured IgG2 subclass mAb, derived from the murine immunoglobulin G1, or IgG1, parent, ACU3B3. Sabirnetug is the result of over a decade of research and development undertaken by the Company, which included a drug discovery partnership with Merck & Co., Inc., or Merck, from 2003 to 2011. Sabirnetug's mechanism of action is intended to slow disease progression and potentially preserve or improve memory function in early AD patients by binding to AßOs and neutralizing their toxicity. AßOs have been shown to bind to neurons, contributing to synaptic malfunction, memory deficits, cognitive impairment and, ultimately, neurodegeneration and cell death. As such, we believe AßOs are the most toxic and pathogenic form of Aß in the brains of AD patients relative to other forms of amyloid, including Aß monomers and amyloid plaques. We believe the development and commercialization of a drug that reduces toxicity of AßOs is one of the most promising approaches for the potential treatment and prevention of the progression of AD. The target population for sabirnetug and other mAbs approved and in development is what is now being called "early AD." This population includes people with a clinical diagnosis of MCI or mild dementia due to AD who are also amyloid positive based on either imaging studies or cerebrospinal fluid, or CSF, biochemical analyses. The term "mild cognitive impairment or mild dementia due to AD" has also been used and is accepted by regulators as an inclusion/exclusion criterion in clinical trials. While epidemiologic studies of this population are evolving, approximately four to five million people in the United States are likely to have early AD who also exhibit amyloid pathology associated with AD.

We are currently developing sabirnetug for IV administration Q4W for the treatment of early AD, and we have begun developing sabirnetug for subcutaneous administration as well. We believe that sabirnetug represents a differentiated approach from current and prior anti-Aß/plaque immunotherapies because it is highly selective for soluble toxic AßOs, which may increase the potential for greater efficacy. In our nonclinical studies using an enzyme-linked immunosorbent assay, or ELISA assay, we observed that sabirnetug has over 500-fold greater selectivity for AßOs compared to Aß monomers, and 87-fold greater selectivity for AßOs over Aß fibrils, and limited or no binding to amyloid plaques. In 2024, we completed a nonclinical study using Surface Plasmon Resonance, or SPR, technology, which demonstrated that sabirnetug has up to 8750-fold greater selectivity for AßOs than Aß monomers and compares favorably to other monoclonal antibodies recently approved by the FDA for the treatment of AD. In immunohistochemical studies of human AD brain tissue, sabirnetug appears to have limited binding to amyloid plaques. Sabirnetug has also demonstrated in vivo biochemical and behavioral activity in several AD mouse models, and safety toxicology studies in rats and monkeys provide acceptable margins for acute and chronic dosing in the clinic.

We believe that sabirnetug is the most advanced immunotherapy candidate in development that was designed to selectively target toxic AßOs. Sabirnetug has additional characteristics that make it a promising potential treatment for AD relative to other antibodies that lack selectivity for AßOs. Sabirnetug is designed to have reduced immune effector function signaling and to avoid binding to vascular amyloid plaques, which we expect will reduce the incidence of ARIA as compared to amyloid plaque-targeting immunotherapies approved and in development for AD. We expect to announce top-line results for ALTITUDE-AD, our Phase 2 clinical trial, in late 2026, following positive results from INTERCEPT-AD, a proof of mechanism Phase 1 clinical trial involving early AD patients, in July 2023. We also announced the results of a Phase 1 clinical trial investigating a subcutaneous dosing option of sabirnetug in healthy volunteers in March 2025.

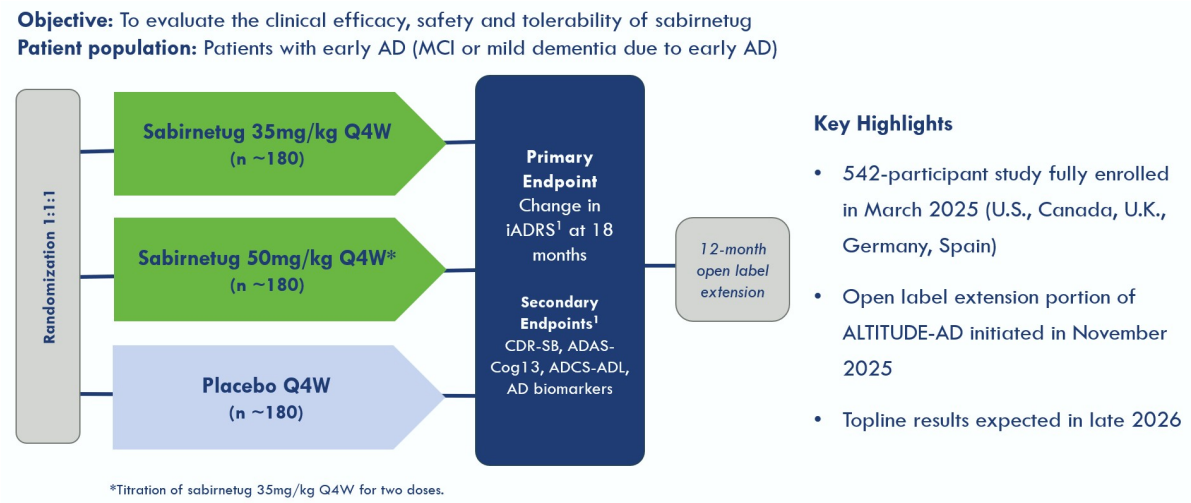
Clinical Development Plan

ALTITUDE-AD

As noted above, we expect to announce topline results of our Phase 2 clinical trial, ALTITUDE-AD, in late 2026. ALTITUDE-AD is a randomized, double-blind, placebo-controlled, three-arm clinical trial designed to evaluate the clinical efficacy, safety and tolerability of sabirnetug, with a total of 542 participants with MCI or mild dementia due to AD. We intend to use iADRS, a measurement of cognitive and functional decline, at 18 months as the primary outcome measure.

The doses for ALTITUDE-AD are 35 mg/kg and 50 mg/kg, both dosed IV Q4W. Participants randomized to the 50 mg/kg dose are being administered 35 mg/kg for the first two doses, which is then increased to 50 mg/kg. The 35 and 50 mg/kg doses were selected based on extensive PK/PD modeling of our Phase 1 clinical trial data.

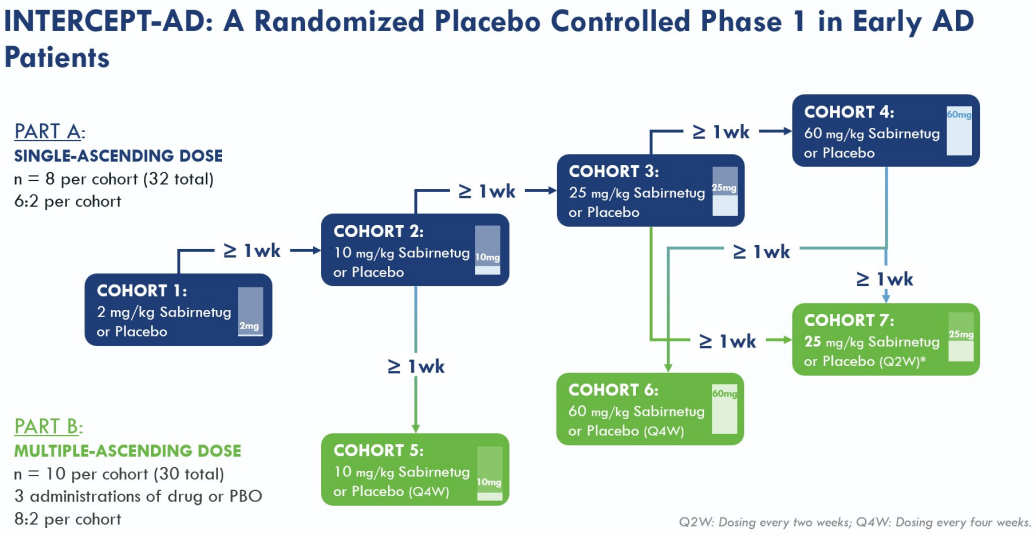
Figure 1. Design of ALTITUDE-AD



INTERCEPT-AD

We reported topline results from INTERCEPT-AD, a U.S.-based, multi-center, randomized, placebo-controlled, SAD and MAD Phase 1 clinical trial of sabirnetug in July 2023. This trial enrolled 65 participants with early AD, and 62 participants received at least one dose of study drug. The early AD patient group was comprised of individuals who have mild dementia or MCI due to AD, and our trial excluded patients with moderate to severe AD dementia. Patients were enrolled across seven cohorts, consisting of a SAD in Part A and an overlapping MAD in Part B. Part A contained Cohorts 1 through 4; each cohort received a single IV dose between 2 mg/kg and 60 mg/kg, or placebo. Part B contained Cohorts 5 through 7; each cohort received a total of three doses of sabirnetug or placebo as follows: 10 mg/kg Q4W, 60 mg/kg Q4W, or 25 mg/kg Q2W.

Figure 2. Design of INTERCEPT-AD



Trial Design Part A - Single Ascending Dose

In Part A of our clinical trial, participants were randomized in a 6:2 ratio into one of four cohorts to receive a single dose of sabirnetug or placebo as follows:

- Cohort 1: One IV dose of sabirnetug (2 mg/kg) or placebo.
- Cohort 2: One IV dose of sabirnetug (10 mg/kg) or placebo.
- Cohort 3: One IV dose of sabirnetug (25 mg/kg) or placebo.
- Cohort 4: One IV dose of sabirnetug (60 mg/kg) or placebo.

The double-blind treatment period for Cohorts 1-4 of Part A was approximately 20 weeks and included 10 visits (four inpatient and six outpatient). A sequential dosing scheme was followed for each cohort in Part A. Dosing of Cohorts 1-3 began at least one week after all participants in the immediately preceding lower-dose cohort had received one administration of study drug and safety data had been reviewed by our internal blinded safety team. Dosing of Cohort 4 began at least one week after all participants in Cohort 3 received one administration of study drug and these safety data, along with Cohort 2 aggregate PK data, had been reviewed by our internal blinded safety team. An unblinded, independent Data Monitoring Committee, or DMC, also monitored safety data in the trial and was able to review data on an ad hoc basis if requested by the blinded study team.

Trial Design Part B - Multiple Ascending Dose

In Part B of our clinical trial, participants were randomized in an 8:2 ratio into one of three cohorts to receive a total of three doses of sabirnetug or placebo as follows:

- Cohort 5: One IV dose of sabirnetug (10 mg/kg) or placebo once Q4W.
- Cohort 6: One IV dose of sabirnetug (60 mg/kg) or placebo once Q4W.
- Cohort 7: One IV dose of sabirnetug (25 mg/kg) or placebo once Q2W.

Participants in Cohorts 5 and 6 were evaluated over approximately 35 weeks, consisting of a seven-week screening period followed by a 28-week, double-blind treatment period.

Participants in Cohort 7 were evaluated over approximately 31 weeks, consisting of a seven-week screening period, followed by a 24-week, double-blind treatment period.

In order to maintain participant safety for Part B of the clinical trial, dosing of Cohort 5 began at least one week after all participants in Cohort 2 of Part A had received one administration of sabirnetug or placebo and the Cohort 2 safety data had been reviewed by our internal blinded safety team. For Cohort 6, dosing began at least one week after all participants in Cohort 4 of Part A had received one administration of sabirnetug or placebo and the Cohort 4 safety data had been reviewed by our internal blinded safety team. Dosing of Cohort 7 began after review of Cohort 3 and Cohort 4 safety data at least one week after the last person in the cohort was dosed. If a potential safety signal, an unexpected adverse reaction, or higher than expected exposure had occurred, our internal blinded safety team would have notified the independent, unblinded DMC to review the safety and PK data and advise on dose escalation. Cohort 7 allowed for additional PK modeling to more accurately determine if Q2W dosing is necessary and if accumulation of sabirnetug occurs with this dosing frequency.

Endpoints

Our Phase 1 clinical trial established clinical proof of mechanism of sabirnetug in patients with early AD. The endpoints we measured as part of this trial included:

Primary Endpoint

- safety and immunogenicity, including assessment for ARIA.

Secondary Endpoints and Exploratory Objectives

- pharmacokinetics in plasma;
- determination of CSF concentrations of sabirnetug;

- evaluation of central target engagement as measured by levels of sabirnetug AßO complex in CSF;
- evaluation of possible changes in concentration of biomarkers for AD in CSF or blood;
- evaluation of possible changes in amyloid plaque load as determined by PET imaging;
- exploratory evaluation of possible changes in cerebral blood flow as determined by MRI, using ASL pulse sequence; and
- exploratory evaluation of possible changes in cognitive, functional and behavioral measures using computerized testing and standard clinical measures for AD.

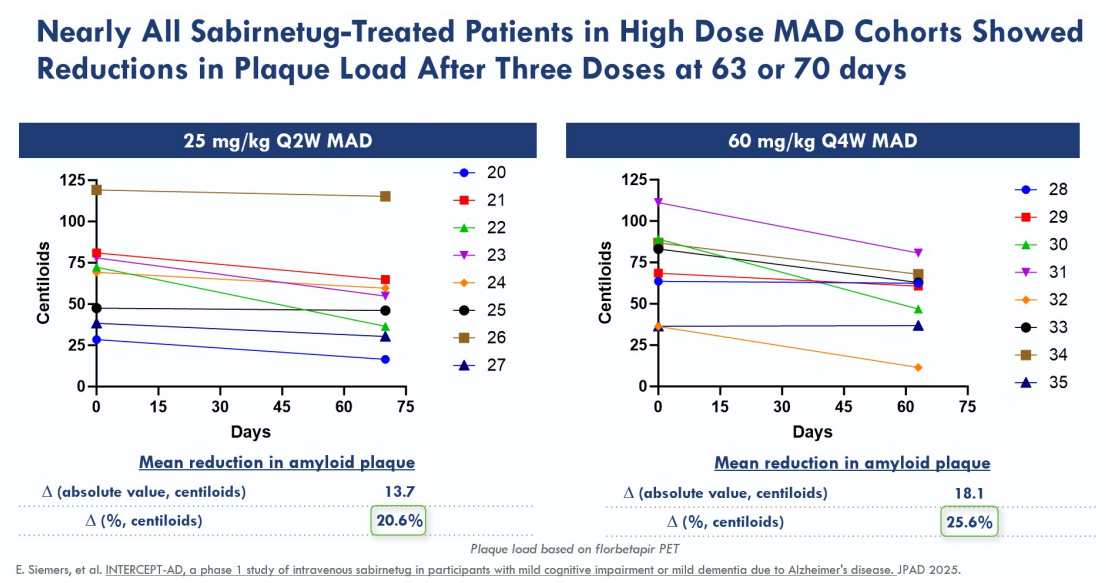
The main objective of INTERCEPT-AD was to evaluate the safety, tolerability, PK, PD, and target engagement of single and multiple ascending doses of sabirnetug administered by IV infusion. Exploratory outcomes included cognitive scales and computerized cognitive testing. Our goal was to establish clinical proof of mechanism of sabirnetug in early AD patients in order to enable progression into further clinical development.

Results

We announced INTERCEPT-AD topline data in July of 2023, which demonstrated that sabirnetug met the primary and secondary objectives of this clinical trial in 62 participants with early AD.

- An analysis of change in amyloid plaque load, as measured by PET Centiloids, demonstrated a rapid, dose-related mean decrease at the higher dose levels studied. Sabirnetug (60 mg/kg Q4W and 25 mg/kg Q2W) showed a statistically significant reduction in amyloid plaque load as determined by amyloid PET after 6-12 weeks (from baseline to endpoint within cohorts (p=0.01)). This finding provides evidence that sabirnetug is active in the brain.

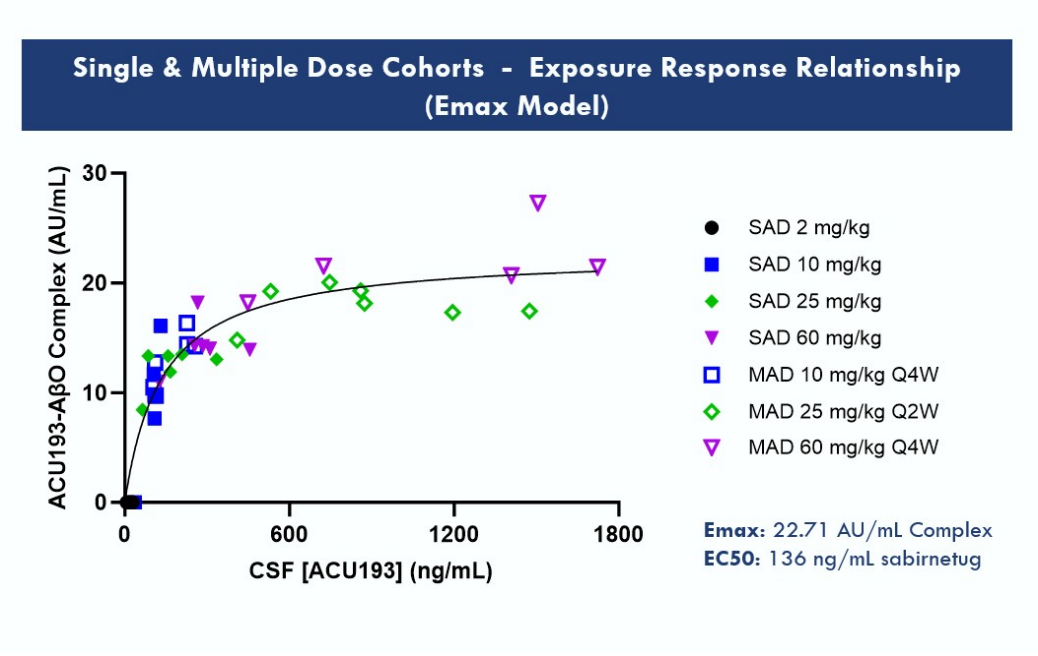
Figure 3. INTERCEPT-AD plaque reduction observed in highest dose MAD cohorts



- Sabirnetug was well-tolerated throughout the SAD and MAD dose cohorts. Three treatment-emergent serious adverse events were observed after administration of sabirnetug; all were deemed not related or unlikely to be related to sabirnetug. The most common treatment-emergent adverse events from all dose groups combined were ARIA-E (10.4%), ARIA-H (hemorrhage) (8.3%), COVID-19 (6.3%), and hypersensitivity (6.3%). The overall rate of ARIA-E was 10.4%, which included one case of symptomatic ARIA-E (2.1%). Of note, no apolipoprotein E homozygote patients exhibited ARIA-E (n=6 treated).
- PK results in CSF demonstrated statistically significant dose proportionality. Serum PK was dose-related without drug accumulation, and CSF PK was dose- and dose-regimen proportional. Levels of sabirnetug detected in CSF in all cohorts were in excess of endogenous levels of AßOs reported in CSF. Evidence of treatment emergent immunogenicity was observed; anti-drug antibodies were consistently low titer and there was no apparent effect on serum PK. These data support monthly dosing of sabirnetug.

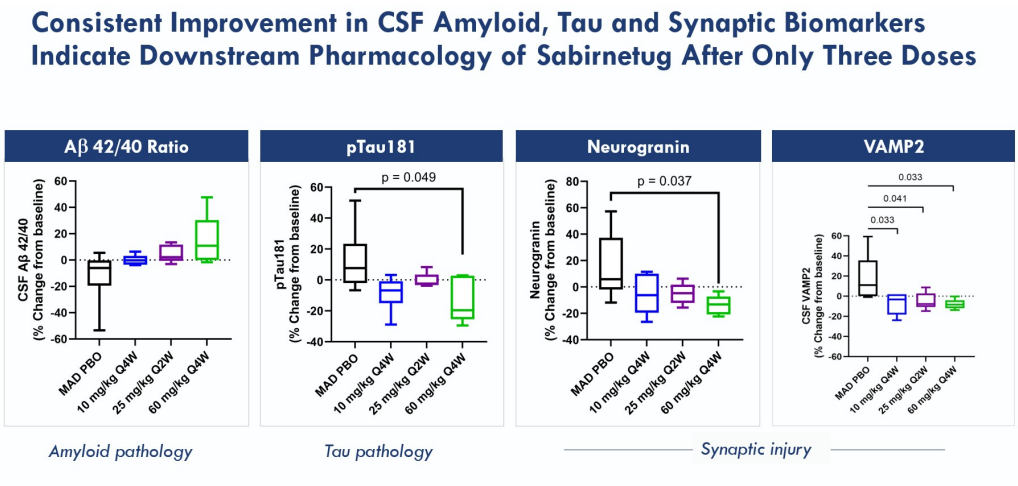
- Statistically significant, dose-related central target engagement was observed as measured by sabirnetug-AßO complex, establishing the first target engagement assay developed that is specific to an AßO-targeting antibody. An exposure response relationship (Emax) model revealed near maximal target engagement with repeated dosing at 25 mg/kg and 60 mg/kg.

Figure 4. Near maximal target engagement of AßOs observed in INTERCEPT-AD



- Exploratory measures of potential acute drug effects including assessment of cognition, as determined by a computerized cognitive battery, and changes in cerebral blood flow, as determined by ASL with MRI (Siemens MRI), did not show discernible effects from the immediate administration of sabirnetug. This was not unexpected due to the short duration and small sample size of INTERCEPT-AD.
- Biofluids for assessment of biomarkers of downstream neurodegeneration were collected during the clinical trial.
    - A dose-dependent trend was observed in the MAD cohorts toward sabirnetug effect on CSF biomarkers specific to amyloid and tau pathology and synaptic injury. These included p-tau181, total tau, neurogranin, VAMP2 and the Aß-42/40 ratio. At the 60 mg/kg Q4W dose of sabirnetug, nominally statistically significant improvements in p-tau181 and neurogranin were observed as compared to the placebo group (p=0.049 and p=0.037, respectively). At all doses, statistically significant improvement in VAMP2 was observed compared to placebo (p=0.033 for the 10 mg/kg dose, p=0.041 mg/kg for 25 mg/kg dose and p=0.033 for the 60 mg/kg dose). Nominally significant correlation was also observed between target engagement of AßOs and change in CSF neurogranin across all doses, and a trend was seen for target engagement versus CSF p-tau181.

Figure 5. CSF biomarker changes observed in INTERCEPT-AD



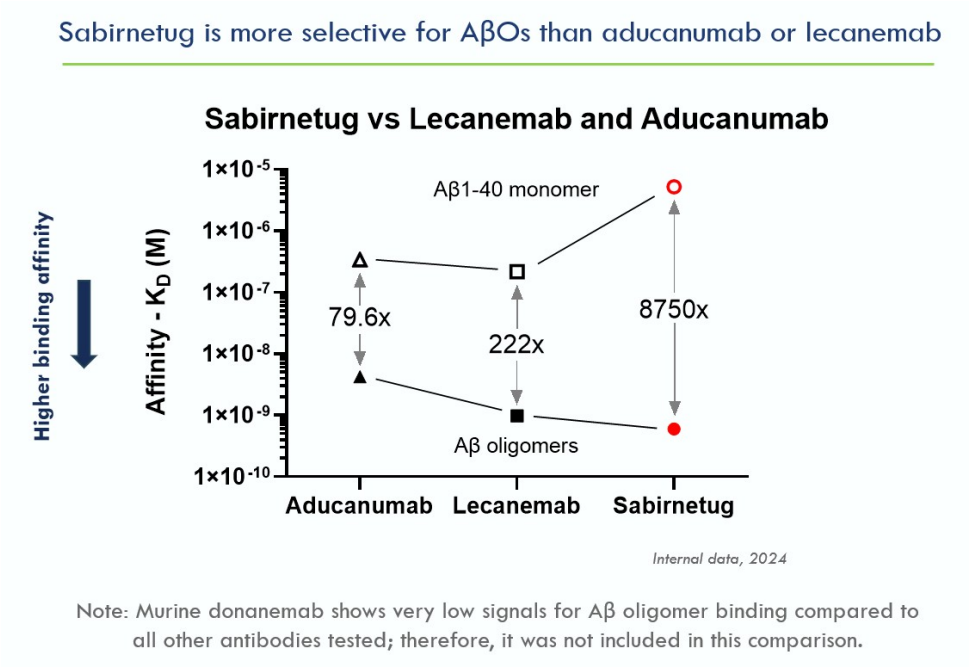
- At the 60 mg/kg MAD cohort of sabirnetug, consistent trends were observed in plasma biomarkers, including glial fibrillary acidic protein, p-tau181 and p-tau217. After dosing completed, biomarkers also rebounded toward placebo, further supportive of a drug effect of sabirnetug.

In October of 2023, we met with the FDA to discuss the ALTITUDE-AD clinical trial design, and the potential pathway for registration of sabirnetug. The FDA had previously granted Fast Track designation to ACU193 in October 2022.

Nonclinical and Laboratory Data

In nonclinical studies, sabirnetug has demonstrated promising characteristics that indicate its potential to bind to AßOs as a possible therapeutic treatment of AD. Early studies showed that sabirnetug has high selectivity, with over 500-fold greater binding selectivity for AßOs compared to Aß monomers, 87-fold greater selectivity for AßOs over Aß fibrils, and limited or no binding to amyloid plaques. More recent SPR data demonstrated that sabirnetug has up to 8750-fold greater selectivity for AßOs over Aß monomers and compares favorably to other monoclonal antibodies recently approved by the FDA for the treatment of AD (Figure 6). Sabirnetug binds to a broad spectrum of small to large soluble AßOs. Additionally, sabirnetug has been shown to offer protection from synaptic toxicity by inhibiting binding of AßOs to primary hippocampal neurons. Sabirnetug has also demonstrated suitable in vivo pharmacology, target engagement, blood-brain barrier penetration and reduction of behavioral deficits in transgenic mouse studies. Lastly, Good Laboratory Practice, or GLP, toxicity studies conducted in two animal species supported the Phase 1 clinical trial. We believe these data, combined with our Phase 1 clinical trial results, indicate that sabirnetug has the potential to offer patients a reduction in cognitive decline.

Figure 6. Relative Selectivity for AßO versus Monomeric Aß Measured with SPR



Selectivity for AßOs

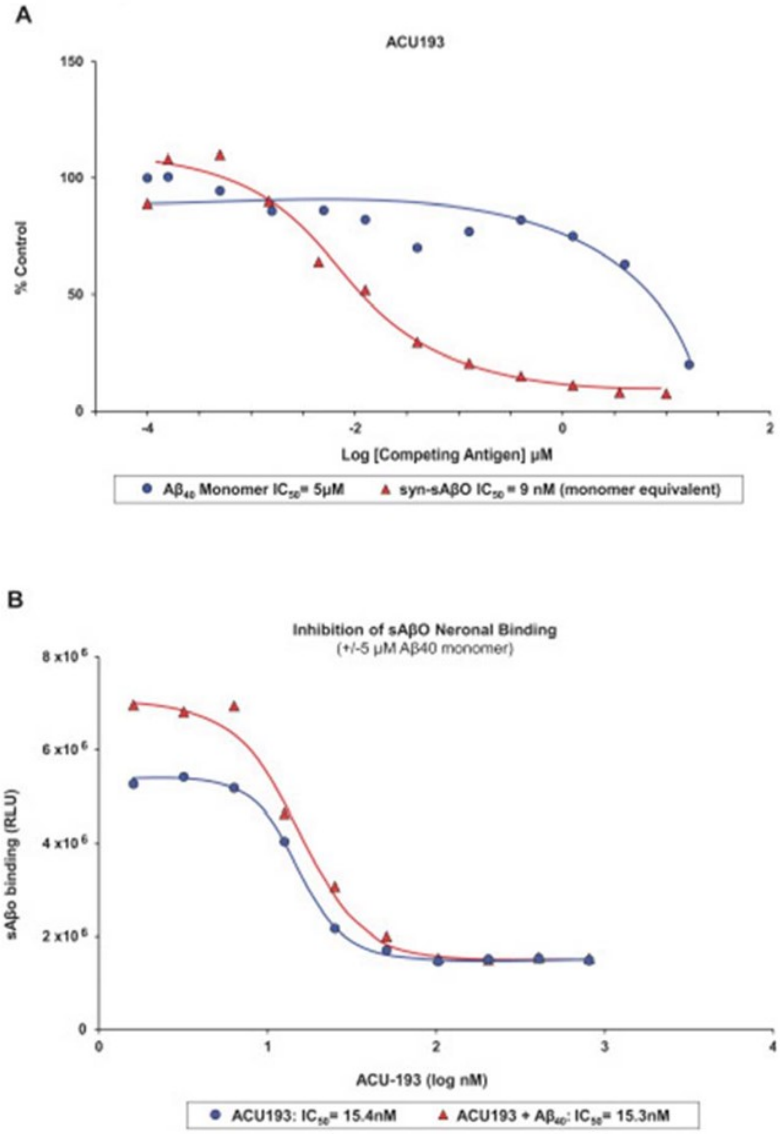
In order to understand sabirnetug selectivity for AßOs, we performed biochemical assays and immunohistochemistry experiments.

Selectivity for AßOs versus Aß monomers

We demonstrated that sabirnetug shows significant preferential selectivity for AßOs compared to Aß monomers. In a competition ELISA assay, sabirnetug's binding to AßOs was 556-fold greater than sabirnetug's binding to Aß monomers. Figure 7[A] shows comparative syn-AßO versus Aß monomer affinity data for sabirnetug and illustrates the high selectivity of sabirnetug for AßOs. Further evidence of sabirnetug selectivity for synthetic-AßOs, or syn-AßOs, was obtained using a very high concentration of monomeric Aß, 5 µM, which did not decrease binding to syn-AßOs (Figure 7[B]). We believe sabirnetug's selectivity for AßOs in the presence of abundant Aß monomers is representative of the in vivo levels of these Aß species in AD patients.

Thus, sabirnetug does not experience "target distraction" from non-toxic Aß monomers in an environment simulating brain interstitial fluid.

Figure 7. [A] Competitive ELISA for sabirnetug binding to syn-AßO or monomeric Aß40 [B] 5µM monomeric Aß did not substantially change binding to syn-AßO

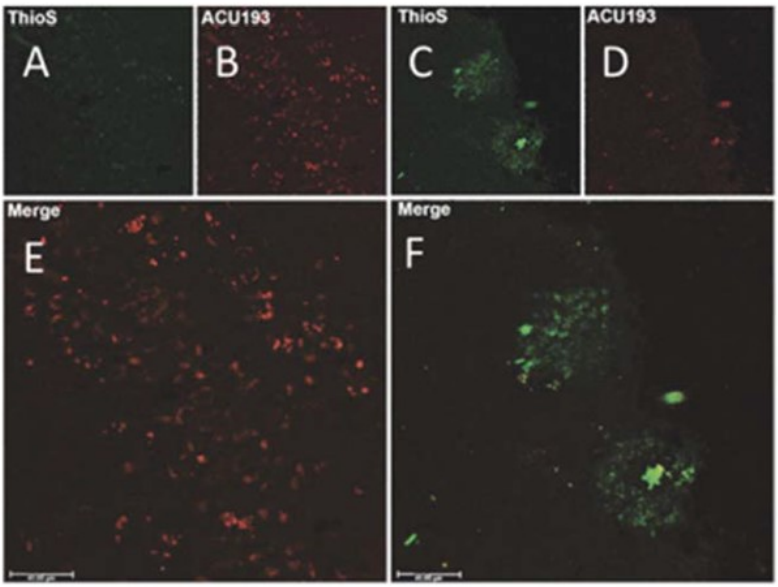


These results support the conclusion that selectivity of sabirnetug for AßOs is maintained in a biochemical environment simulating the brain.

Selectivity for AßOs versus amyloid plaques

We have shown in our human immunohistochemistry studies that sabirnetug binds AßOs from AD patients with limited or no binding to amyloid plaques. In Figure 8 below, thioflavin S-positive ß-amyloid plaques are shown in green fluorescence while sabirnetug binding is shown in red fluorescence. Sabirnetug binds significantly in regions that are thioflavin-S-negative, i.e., without amyloid plaques (Figure 8, Panels B and E), but only infrequently and minimally may bind to thioflavin-S-positive fibrillar Aß structures in their periphery (Figure 8, Panels D and F). Taken together, these results are consistent with the concept that sabirnetug binds endogenous AßOs, and preferentially binds AßOs versus fibrillar Aß.

Figure 8. Sabirnetug binding to AßOs versus amyloid plaques

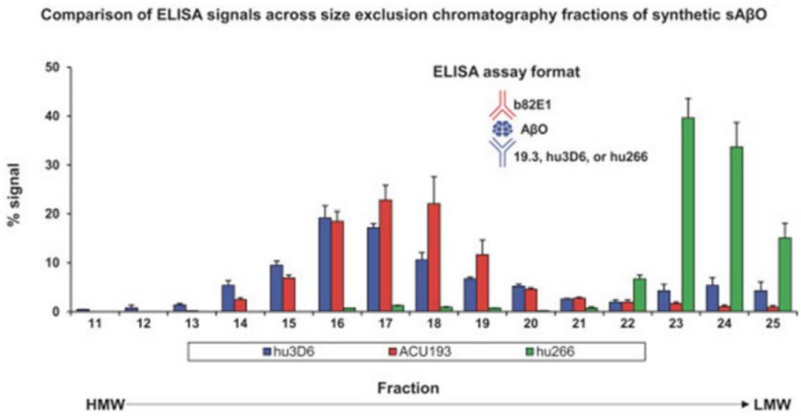


The upper left portion of the immunohistochemistry figure shows that in areas with no amyloid plaque binding (no green fluorescence staining, Panel A) there is substantial binding by sabirnetug (red fluorescence staining, Panel B) that is not related to amyloid plaque. The merge of these panels (Panel E) shows sabirnetug binding with no amyloid plaque present. On the upper right portion of the figure, the area that is positive for amyloid plaque (green fluorescence staining, Panel C) shows minimal sabirnetug binding (red fluorescence staining, Panel D). The merge of these panels (Panel F) shows the minimal binding of sabirnetug (red fluorescence staining) on the periphery of the amyloid plaque (green fluorescence staining), which may be related to AßO binding in the halo of the amyloid plaque.

Binding to a broad spectrum of molecular weight AßOs

In addition, we demonstrated that sabirnetug binds a broad spectrum of AßOs across various molecular weights. In another series of experiments, syn-AßOs were fractionated by size exclusion chromatography and characterized by ELISA using sabirnetug, hu3D6 (bapineuzumab) or hu266 (solanezumab) as the capture antibody and biotinylated anti-human Aß antibody 82E1 for detection. These data show sabirnetug binds AßOs ranging from dimers to approximately 100-mers, with preferential binding to mid-molecular weight oligomers compared to hu266.

Figure 9. Binding of humanized antibodies to size exclusion chromatography fractions of synthetic Aß species



Size exclusion chromatography fractionation of syn-AßO prep with sandwich ELISA detection. hu3D6 is also known as bapineuzumab; hu266 is also known as solanezumab. These data demonstrate the specificity of sabirnetug for oligomers versus monomers, and also demonstrate a range of oligomers that are bound by sabirnetug.

Collectively the data show that sabirnetug binds AßOs with 556-fold selectivity versus Aß monomers and demonstrates limited to no binding to amyloid plaques, but does bind to a broad range of synthetic and endogenous low, mid, and higher molecular weight AßOs. Based on these and our target engagement data demonstrated in our INTERCEPT-AD Phase 1 clinical trial data, we believe that sabirnetug can target therapeutically relevant AßOs in the brains of early AD patients.

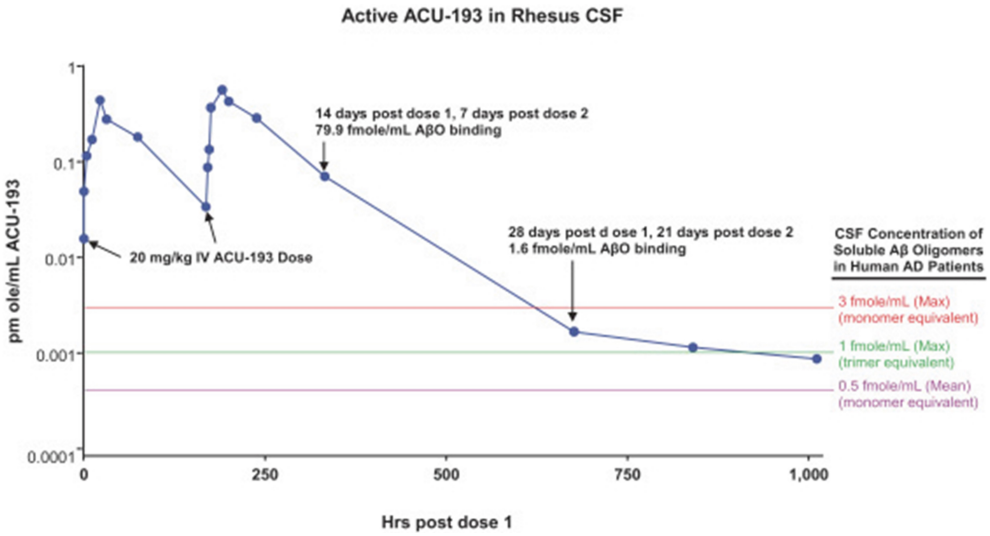
In Vivo Pharmacology

In order to understand the effects of sabirnetug in intact animals, we performed behavioral studies in transgenic mice with genetic alterations that overproduce a mutant APP that forms amyloid plaques. The transgenic mouse models are generally based on autosomal dominant mutations in the APP gene causing rare forms of human AD. Transgenic mouse models using these mutations may not cause the full spectrum of AD pathology, but they do provide relevant animal models for drug development in AD. Taken together, these behavioral studies, performed at three different laboratories, indicate in vivo central pharmacologic activity of peripherally administered ACU3B3. The behavioral effects seen in these studies indicate that sufficient amounts of ACU3B3 cross the blood-brain barrier to engage the target, resulting in behavioral improvements in these transgenic mice.

Pharmacokinetics and Pharmacodynamics

A study of PK in CSF was conducted in rhesus monkeys. An intrathecal catheter was implanted in the monkeys, and two doses at 20 mg/kg IV were administered. As shown in Figure 10, the concentrations of sabirnetug in CSF should provide adequate target engagement with dosing Q4W. This was recapitulated in our INTERCEPT-AD Phase 1 results, which demonstrated near-maximal target engagement of AßOs at both 25 mg/kg Q2W and 60 mg/kg Q4W.

Figure 10. Comparison of sabirnetug levels in rhesus CSF to CSF Levels of AßO in human AD patients



Following two doses of 20 mg/kg sabirnetug CSF concentrations were sufficient to provide target engagement at 28 days. An estimate of 1 fmole/mL for oligomer concentration is conservative given that it is based on AßOs consisting of trimers.

Safety Profile

GLP studies using IV administration of sabirnetug established a no-observed-adverse-effect level, or NOAEL, of 250 mg/kg/dose, which was the maximum feasible dose, given Q2W in a 28-day study in Sprague-Dawley rats. The NOAEL in cynomolgus monkeys was 300 mg/kg/dose in a 14-week study in cynomolgus monkeys using IV dosing Q2W. In Sprague Dawley rats, no adverse findings were noted. In the 14-week study in cynomolgus monkeys, doses of 60, 300 or 600 mg/kg/dose sabirnetug once Q2W were administered. Three animals administered the highest 600 mg/kg/dose were sacrificed early for humane reasons on Days 43 or 60 due to sabirnetug-related, anaphylactoid-type reactions.

Thus, the 300 mg/kg/dose is considered the NOAEL for cynomolgus monkeys. The NOAELs of 300 mg/kg and 250 mg/kg compare favorably to the highest dose of sabirnetug that was used in our Phase 1 clinical trial (60 mg/kg) and the doses chosen for our Phase 2 clinical trial (30 and 50 mg/kg).

With regard to effector function and possible inflammatory effects generally, sabirnetug is an IgG2 subclass antibody which has limited inflammatory effector function signaling compared to other IgG subclasses.

Combination Potential

While we believe sabirnetug, if successful, will likely be a foundational treatment for people with early AD, it also could be used as part of a combination treatment regimen, including with EBD technology. The pathology of AD is complex, and many experts in the field expect that combination therapy using disease-modifying drugs with different mechanisms of action, such as tau, immune modulation, glial cells such as microglia and astrocytes, and growth factors, will ultimately prove most successful, similar to cutting edge approaches used in oncology. In addition, because symptomatic treatments, such as memantine and cholinesterase inhibitors, affect neurotransmitter systems rather than the underlying AD pathology, we believe that they can be used together with disease-modifying treatments.

Manufacturing

We do not currently own or operate facilities for product manufacturing, storage and distribution, or testing. We contract with third parties for the manufacture of sabirnetug. Because we rely on contract manufacturers, we employ personnel with extensive technical, manufacturing, analytical and quality experience. Our staff has strong project management discipline to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

Manufacturing is subject to extensive regulation that imposes various procedural and documentation requirements and that governs record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, and more. Our systems and our contractors are required to be in compliance with these regulations, and compliance is assessed regularly through monitoring of performance and a formal audit program.

Our current supply chains for sabirnetug involve several manufacturers that specialize in specific operations of the manufacturing process, including raw materials manufacturing, drug substance manufacturing and drug product manufacturing. We currently operate under work order programs for sabirnetug with master services agreements in place that include specific supply timelines, volume and quality specifications. We believe our current manufacturers have the scale, the systems and the experience to supply our currently planned clinical trials.

Competition

In June 2021, the FDA granted approval for Biogen Inc.'s, or Biogen's, Aduhelm® (aducanumab) under the FDA's Accelerated Approval Pathway, or AAP. Aduhelm was the first new AD product approval since 2004 and the first approved disease-modifying product. In April 2022, the Centers for Medicare and Medicaid Services, or CMS, released a final National Coverage Decision that restricts reimbursement for mAbs directed against amyloid for the treatment of AD, including Aduhelm, under a Coverage with Evidence Development, or CED, designation. The CED designation limits reimbursement of anti-amyloid antibodies, including Aduhelm, to placebo-controlled clinical trials. In May 2022, Biogen announced its decision to eliminate substantially all commercial support for Aduhelm in the United States and withdrew its marketing application for Aduhelm in Europe. In January 2024, Biogen announced its decision to discontinue the development and commercialization of Aduhelm.

In September 2022, Eisai Co., Ltd., or Eisai, announced results from its Leqembi® (lecanemab) Phase 3 CLARITY-AD trial. Leqembi is a recombinant humanized IgG1 mAb directed against aggregated soluble (protofibrils) and insoluble (plaque) forms of Aß. In CLARITY-AD, Leqembi demonstrated highly statistically significant effects on primary and secondary clinical measures (including a 27% slowing of cognitive decline as measured by CDR-SB) and a lower rate of ARIA-E (12.6%) than observed for aducanumab in the Phase 3 EMERGE and ENGAGE studies. In January 2023, the FDA granted approval for Leqembi under the AAP based on results of its Phase 2 clinical trial. In July 2023, the FDA approved the supplemental Biologics License Application, or BLA, supporting the approval of Leqembi. Also in July 2023, CMS announced it would cover Leqembi when a physician and care team participates in a CMS-facilitated registry. While this approval and coverage determination are encouraging developments, the need for additional options for AD treatment and prevention becomes more urgent with each passing year, and we believe that our novel approach can potentially help

address this pressing need. In August 2025, the FDA approved once-weekly subcutaneous maintenance dosing of Leqembi in patients with early AD following an 18-month intravenous induction period. Moreover, in January 2026, Eisai and Biogen announced that the FDA granted priority review for a subcutaneous starting dose of Leqembi with a Prescription Drug User Fee Act date of May 24, 2026.

In January 2023, the FDA issued a complete response letter, or CRL, to Eli Lilly and Company, or Eli Lilly, for the accelerated approval submission of donanemab. In May 2023, Eli Lilly announced results from its donanemab Phase 3 TRAILBLAZER-ALZ 2 trial. Donanemab is an IgG1 mAb that specifically targets deposited amyloid plaque. In the TRAILBLAZER-ALZ 2 trial, donanemab demonstrated highly statistically significant effects on primary and secondary clinical measures (including a 29% slowing of cognitive decline, as measured by CDR-SB in its high and intermediate tau patient group) with a higher rate of ARIA-E (24%) among all donanemab-treated patients when compared to Leqembi. In July 2024, the FDA approved Kisunla® (donanemab) for the treatment of early AD, and in July 2025, due to the results of the TRAILBLAZER-ALZ 6 study, a modified titration schedule for donanemab was approved and the label was updated, indicating an incidence of ARIA of 14% among donanemab-treated patients by week 24.

There have been no comprehensive head-to-head clinical trials between any of the product candidates discussed above. Study designs and protocols for each product candidate were different, and results may not be comparable among product candidates.

We face competition from several different institutions, including pharmaceutical and biotechnology companies, research institutions, governmental organizations and universities developing novel therapies for AD. We believe that the key factors affecting the clinical and commercial success of sabirnetug will include safety profile, efficacy, method of administration, level of marketing activity, insurance reimbursement and intellectual property protection.

If approved, sabirnetug can be used in combination with therapies currently approved for the treatment of AD that treat the symptoms of AD rather than the underlying cause of the disease, such as memantine and cholinesterase inhibitors.

Other companies known to be developing therapies with Aß-, AßO- and amyloid plaque-related targets include AbbVie Inc., or Abbvie, Alector, Inc., or Alector, Alnylam Pharmaceuticals, Inc., AltPep Corporation, Alzheon, Inc., Alzinova AB, BioArctic AB, Biogen, Bristol-Myers Squibb Company, Cognition Therapeutics, Inc., Denali Therapeutics, Inc., or Denali, Eisai, Eli Lilly, Grifols, S.A., Korsana Biosciences, Inc., Neurimmune AG, Priavoid GmbH, ProMIS Neurosciences, Inc., Prothena Biosciences, Inc., Roche Holding AG (including Genentech, Inc., its wholly-owned subsidiary), or Roche, and Wavebreak Therapeutics, Inc. Additionally, sabirnetug, if approved, may also compete with other potential therapies intended to address underlying causes of AD that are being developed by several companies, including AbbVie, AC Immune SA, Alector, Anavex Life Sciences Corp., Annovis Bio, Inc., Biogen, Biohaven Pharmaceuticals, Inc., Cassava Sciences, Inc., Denali, Eisai, Johnson & Johnson (including Janssen Inc., its wholly-owned subsidiary), H. Lundbeck A/S, Lighthouse Pharmaceuticals, Inc., Roche and Takeda Pharmaceutical Co. Ltd.

Additional Treatment Modalities

While Aß and amyloid are generally considered to be the proximal causes of AD pathology, and alternative hypotheses to the amyloid hypothesis propose that amyloid accumulation is a consequence of other processes such as infection and that other pathogens lead to amyloid accumulation, downstream targets such as tau, inflammation-related targets and growth factors may eventually be useful approaches in the treatment of AD and are being explored. Some of these treatment modalities have made nonclinical and early-stage clinical progress, although these efforts are still significantly less advanced than those approaches targeting Aß or amyloid plaques.

Collaboration Agreement with Merck

In December 2003, we entered into an exclusive license and research and development collaboration agreement with Merck to research, discover and develop certain technology related to Aß-derived diffusible ligands, or ADDLs, which agreement was amended and restated in October 2006. The agreement generally provided that, during the course of the collaboration, Merck would be responsible for the preclinical and clinical development and commercialization of any products covered by the agreement and, in return, we were eligible to receive potential nonclinical, clinical and regulatory milestone payments and royalties on future product sales. During the collaboration, Merck developed sabirnetug, an ADDL antibody, and intellectual property related to sabirnetug was filed by Merck. In 2011, Merck elected to voluntarily terminate the collaboration agreement. Pursuant to the surviving provisions of the agreement, effective upon termination of the collaboration, Merck granted us an exclusive, perpetual, irrevocable, royalty-free, worldwide license, with right to

sublicense, under Merck's interest in the patent rights and know-how necessary for the research, development, manufacturing or commercialization of ADDL antibodies, ADDL antigens or products, including sabirnetug.

License Agreement with Lonza

On November 2, 2022, the Company entered into a license agreement, or the Lonza License Agreement, with Lonza Sales AG, or Lonza. Under the terms of the Lonza License Agreement, Lonza granted the Company a worldwide non-exclusive license to use Lonza's glutamine synthetase gene expression system to manufacture and commercialize sabirnetug, or the Lonza Product.

Pursuant to the Lonza License Agreement, we paid Lonza an upfront fee of 1.0 million Swiss Francs. The Company is also required to pay certain royalties upon commercialization and annual payments on a country-by-country basis in respect of the manufacturing and sale of the Lonza Product, which include (i) a royalty of less than 1.0% on net sales where Lonza manufactures the Lonza Product, (ii) an annual royalty payment in Swiss Francs in the low six-digits and a royalty of less than 1.0% on net sales where the Company manufactures the Lonza Product and (iii) an annual payment in Swiss Francs in the mid six-digits per sublicense and a royalty on net sales in the low single digits where a third party manufactures the Lonza Product. These payment obligations would expire 10 years from the first commercial sales of the Lonza Product in such country of sale.

The Lonza License Agreement continues until terminated, and the Company or Lonza may terminate the Lonza License Agreement for uncured material breaches or insolvency of the other party. The Company can unilaterally terminate the Lonza License Agreement with prior written notice to Lonza, and Lonza can also unilaterally terminate the Lonza License Agreement upon certain actions by the Company. The Lonza License Agreement also contains customary representations, warranties, indemnification and other obligations of the Company and Lonza.

Halozyme License Agreement

On November 5, 2023, the Company entered into a non-exclusive collaboration and license agreement, or the Halozyme License Agreement, with Halozyme. Under the terms of the Halozyme License Agreement, Halozyme granted the Company a non-exclusive license to Halozyme's ENHANZE® drug delivery technology for the development of a subcutaneous formulation of sabirnetug, or the Halozyme Product. Halozyme will also be the Company's exclusive supplier of clinical and commercial supplies of the active pharmaceutical ingredient for Halozyme's PH20 product.

Pursuant to the Halozyme License Agreement, the Company paid Halozyme a seven-figure upfront payment for the license to Halozyme's technology. Additionally, the Company will make milestone payments tied to achievement of certain development and commercialization milestone events with respect to the Halozyme Product, as well as milestone payments based on achievement of certain net sales levels of the Halozyme Product. The Company will also make single-digit royalty payments based on worldwide net sales of the Halozyme Product.

The Halozyme License Agreement includes customary termination rights, representations and warranties, covenants and indemnification obligations for a transaction of this nature.

JCR License Agreement

In July 2025, we entered into a collaboration, option and license agreement with JCR to develop an Aß oligomer-targeted EBD™ therapy for the treatment of AD. Under the terms of the agreement, in addition to an upfront license payment that we paid to JCR, if we exercise our exclusive option to develop up to two development candidates, JCR will be eligible for an option exercise payment of $9.25 million. Our option is expected to be exercised when we have selected or identified up to two preclinical candidates we would license and advance into IND-enabling activities. JCR will also be eligible to receive future milestone payments of up to $40.0 million related to development, and up to $515.0 million related to sales, for a total of up to $555.0 million, as well as single-digit percentage royalties on sales of any products that emerge from the collaboration. The combination of sabirnetug or additional, novel, AβO-selective antibodies with JCR's blood-brain barrier-penetrating technology, J-Brain Cargo®, strengthens Acumen's portfolio of AβO-targeted therapies. The partnership is designed to advance potential next-generation treatment options for people living with AD, by targeting the development of products with enhanced efficacy, safety and convenience.

Intellectual Property

Our intellectual property is critical to our business and we strive to protect it, including by obtaining and maintaining patent protection in the United States and internationally for our product candidate. We also rely on the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors. To help protect our proprietary know-how that is not patentable, we rely on confidentiality agreements to protect our interests. We require our employees, consultants, scientific advisors and contractors to enter into confidentiality agreements prohibiting the disclosure of confidential information and requiring disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

The main form of commercial exclusivity for our product candidate, sabirnetug, is expected to come from biologic regulatory exclusivity. We expect that once approved by regulatory agencies, sabirnetug will receive the benefit of 12 years of market exclusivity in the United States and 10 to 11 years of data and market exclusivity in Europe, in each case, against competitors seeking approval for a biosimilar product.

We have an exclusive license grant from Merck to patents claiming the composition and method of use of our product candidate, sabirnetug. The license grant arose from our collaboration agreement with Merck to research, discover and develop technology related to ADDLs. During our collaboration, sabirnetug, an ADDL antibody, was developed and intellectual property was filed by Merck. In 2011, the collaboration agreement terminated and Merck exclusively licensed to Acumen Merck's interest in patent rights claiming ADDL antibodies, including sabirnetug, ADDL Antigens and/or Products to Acumen. In the nine years subsequent to the termination of the collaboration with Merck, Acumen has controlled and directed and continues to control and direct prosecution of the licensed sabirnetug patent portfolio. Acumen has also paid for and continues to pay all costs and fees associated with the prosecution and maintenance of the licensed sabirnetug patent portfolio.

As of March 27, 2025, Acumen licenses from Merck one issued U.S. patent and 18 issued foreign patents, including issued patents in Brazil, China, Canada, Australia, Japan, South Korea, France, Germany and the UK drawn to our product candidate, sabirnetug. These patents are projected to expire in July 2031, without taking into account any possible extensions and assuming payment of all appropriate maintenance, renewal, annuity or other governmental fees.

Throughout the development of our product candidate, we seek to identify additional means of obtaining patent protection that would potentially enhance commercial success, including by protecting inventions related to additional methods of use, processes of making, formulation and dosing regimens.

Patent Term and Term Extensions

The terms of individual patents are determined based primarily on the date of filing of the patent application or the date of patent issuance and the legal term of patents in the countries in which they are obtained. Generally, utility patents issued for applications filed in the United States are granted a term of 20 years from the earliest effective filing date of a non-provisional patent application. In addition, in certain instances, the term of a U.S. patent can be extended to recapture a portion of the United States Patent and Trademark Office, or USPTO, delay in issuing the patent as well as a portion of the term effectively lost as a result of the FDA regulatory review period. However, as to the FDA component, the restoration period cannot be longer than five years and the restoration period cannot extend the patent term beyond 14 years from FDA approval for the product covered by that patent. In addition, only one patent applicable to an approved drug may receive the extension, and the extension applies only to coverage for the approved drug, methods for using it and methods of manufacturing it, even if the claims cover other products or product candidates. Where one patent covers multiple products or product candidates, it may only receive an extension for one of the covered products; any extension related to a second product or product candidate must be applied to a different patent. The duration of foreign patents varies in accordance with provisions of applicable local law, but typically is also 20 years from the earliest effective filing date of a non-provisional patent application, such as a Patent Cooperation Treaty application. All taxes, annuities or maintenance fees for a patent, as required by the USPTO and various foreign jurisdictions, must be timely paid in order for the patent to remain in force during this period of time.

The actual protection afforded by a patent may vary on a product-by-product basis, from country to country, and can depend upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory-related extensions and the availability of legal remedies in a particular country and the validity and enforceability of the patent.

Our patents and patent applications may be subject to procedural or legal challenges by others. We may be unable to obtain, maintain and protect the intellectual property rights necessary to conduct our business, and we may be subject to

claims that we infringe or otherwise violate the intellectual property rights of others, which could materially harm our business. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Trademarks and Know-How

In connection with the ongoing development and advancement of our products and services in the United States and various international jurisdictions, we seek to create protection for our marks and enhance their value by pursuing trademarks and service marks where available and when appropriate. We rely upon know-how and continuing technological innovation to develop and maintain our competitive position. We seek to protect our proprietary information, in part, by using confidentiality agreements with our commercial partners, collaborators, employees and consultants, and invention assignment agreements with our employees and consultants. These agreements are designed to protect our proprietary information and, in the case of the invention assignment agreements, to grant us ownership of technologies that are developed by our employees and through relationships with third parties. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our contractors, commercial partners, collaborators, employees and consultants use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions. For more information, see the section titled “Risk Factors—Risks Related to Our Intellectual Property.”

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, pricing, reimbursement, post-approval monitoring and post-approval reporting of biologics such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with applicable federal, state, local and foreign statutes and regulations, both pre-approval and post-approval, require the expenditure of substantial time and financial resources. The regulatory requirements applicable to drug and biological product development, approval and marketing are subject to change, and regulations and administrative guidance often are revised or reinterpreted by the agencies in ways that may have a significant impact on our business.

U.S. Biologics Regulation

In the United States, biological products are subject to regulation under the Federal Food, Drug, and Cosmetic Act, or FDCA, the Public Health Service Act and other federal, state and local statutes and regulations. The process required by the FDA before biologics may be marketed in the United States generally involves the following:

- completion of preclinical laboratory tests and animal studies performed in accordance with the FDA’s GLP requirements;
- submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical trials may begin and must be updated annually and when certain changes are made;
- approval by an institutional review board, or IRB, or independent ethics committee at each clinical site before the trial is commenced;
- performance of adequate and well-controlled human clinical trials in accordance with Good Clinical Practices, or GCPs, requirements and other clinical trial-related regulations to establish the safety, purity and potency of the proposed biologic product candidate for its intended purpose;
- preparation of and submission to the FDA of a BLA after completion of all pivotal clinical trials;
- payment of user fees for FDA review of the BLA;
- satisfactory completion of an FDA Advisory Committee review, if applicable;
- a determination by the FDA within 60 days of its receipt of a BLA to file the application for review;
- satisfactory completion of an FDA pre-approval inspection of the manufacturing facility or facilities at which the proposed product is produced to assess compliance with current Good Manufacturing Practices, or cGMPs, and to assure that the facilities, methods and controls are adequate to preserve the biological product’s continued safety, purity and potency, and of selected clinical investigation sites to assess compliance with GCPs; and

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

Failure to comply with the applicable regulatory requirements at any time during the product development process or post-approval may subject an applicant to delays in development or approval, as well as administrative and judicial sanctions.

Preclinical and Clinical Trials

Prior to beginning the first clinical trial with a product candidate, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data, must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational new drug to humans. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises safety concerns or questions about the proposed clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns or questions before the clinical trial can begin.

The FDA may, at any time during the initial 30-day IND review period, or while clinical trials are ongoing, impose a partial or complete clinical hold based on concerns for patient safety and/or noncompliance with regulatory requirements. This order issued by the FDA would delay a proposed clinical study or cause suspension of an ongoing study until all outstanding concerns have been adequately addressed and the FDA has notified the company that investigations may proceed. Imposition of a clinical hold could cause significant delays or difficulties in completing planned clinical studies in a timely manner. Clinical trials involve the administration of the investigational product to human subjects under the supervision of qualified investigators in accordance with GCPs, which include the requirement that all research subjects provide their informed consent for their participation in any clinical study. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the dosing procedures, subject selection and exclusion criteria, and the parameters and criteria to be used in monitoring safety and effectiveness. A separate submission to the existing IND must be made for each successive clinical trial conducted during product development and for any protocol and subsequent protocol amendments. Furthermore, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial and its informed consent form before the clinical trial begins at that site, and must monitor the study until completed. In addition, the IRB or the sponsor may suspend a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk, that the trial is unlikely to meet its stated objectives or that the trial is not being conducted in accordance with FDA requirements. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board or DMC, which provides authorization for whether or not a study may move forward at designated checkpoints based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk to subjects or on other grounds, such as lack of efficacy.

Information about applicable clinical trials, including clinical trials results, must be submitted within specific timeframes for publication on the www.clinicaltrials.gov website.

IND sponsors must submit annual reports on the progress of investigations under the IND to the FDA and submit IND safety reports when certain serious and unexpected adverse reactions and certain other safety issues occur.

For purposes of BLA approval, human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1-The investigational product is initially introduced into a limited population of healthy human subjects or patients with the target disease or condition. These studies are designed to test the safety, dose response, absorption, metabolism and distribution of the investigational product in humans, the side effects associated with increasing doses, and, if possible, to gain early evidence on effectiveness.
- Phase 2-The investigational product is administered to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.

- Phase 3-The investigational product is administered to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of a BLA.

In some cases, the FDA may require, or companies may voluntarily pursue, additional clinical trials after a product is approved. These trials are used to gain additional data from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. These so-called Phase 4 studies may also be made a condition to approval of the BLA.

Concurrent with clinical trials, companies may complete additional animal studies and develop additional information about the biological characteristics of the product candidate and must finalize a process for manufacturing the product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and, among other things, must develop methods for testing the identity, strength, quality and purity of the final product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life and to identify appropriate storage conditions for the product candidate.

BLA Submission and Review by the FDA

Assuming successful completion of all required testing in accordance with all applicable regulatory requirements, the results of product development, nonclinical studies and clinical trials are submitted to the FDA as part of a BLA requesting approval to market the product for one or more indications. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety, purity and potency of the investigational biologic, to the satisfaction of the FDA. FDA approval of a BLA must be obtained before a biologic may be marketed in the United States. The submission of a BLA requires payment of a substantial application user fee to the FDA, unless a waiver or exemption applies.

Within 60 days following submission of the application, the FDA reviews a BLA submitted to determine if it is substantially complete before the FDA accepts it for filing. Once a BLA has been accepted for filing, the FDA's goal is to review standard applications within 10 months after the filing date, or, if the application qualifies for priority review, six months after the FDA accepts the application for filing. In both standard and priority reviews, the review process may also be extended by FDA requests for additional information or clarification.

Before approving a BLA, the FDA will typically inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMPs and adequate to assure consistent production of the product within required specifications. Additionally, before approving a BLA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

After the FDA evaluates a BLA and conducts inspections of manufacturing facilities where the investigational product and/or its drug substance will be produced, the FDA may issue an approval letter or a CRL. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications. A CRL will describe all of the deficiencies that the FDA has identified in the BLA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the CRL without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the BLA in condition for approval, including requests for additional information or clarification. The FDA may delay or refuse approval of a BLA if applicable regulatory criteria are not satisfied, require additional testing or information and/or require post-marketing testing and surveillance to monitor safety or efficacy of a product.

If regulatory approval of a product is granted, such approval will be granted for particular indications and may entail limitations on the indicated uses for which such product may be marketed. For example, the FDA may approve the BLA with a Risk Evaluation and Mitigation Strategy, or REMS, to ensure the benefits of the product outweigh its risks. A REMS is a safety strategy implemented to manage a known or potential serious risk associated with a product and to enable patients to have continued access to such medicines by managing their safe use, and could include medication guides,

physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA also may condition approval on, among other things, changes to proposed labeling, the development of adequate controls and specifications, or the completion of post-marketing studies or surveillance programs.

Expedited Development and Review Programs

The FDA offers a number of expedited development and review programs for qualifying product candidates. These programs include Fast Track designation, Breakthrough Therapy designation, and priority review.

The Fast Track program is intended to expedite or facilitate the process for reviewing new products that 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. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a Fast Track product has opportunities for more frequent interactions with the applicable FDA review team during product development, in addition to the potential for rolling review of the BLA, meaning that the FDA may consider for review sections of the 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 BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the BLA.

A product candidate intended to treat a serious or life-threatening disease or condition may also be eligible for Breakthrough Therapy designation if preliminary clinical evidence indicates that the product candidate, 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 candidate, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any marketing application for a drug or biologic submitted to the FDA for approval, including a product candidate with a Fast Track designation and/or Breakthrough Therapy designation, may be eligible for priority review. A product candidate is eligible for priority review if it is designed to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness compared to available alternatives for such disease or condition. For original BLAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (as compared to 10 months under standard 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.

Accelerated approval pathway

The FDA may grant accelerated approval to a product candidate for a serious or life-threatening condition that provides meaningful therapeutic advantage to patients over existing treatments based on a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality, that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

As a condition of accelerated approval, the FDA will generally require the sponsor to perform adequate and well-controlled post-marketing clinical studies to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. Products receiving accelerated approval may be subject to expedited withdrawal procedures if the sponsor fails to conduct the required post-marketing studies or if such studies fail to verify the predicted clinical benefit. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. FDORA, signed by President Biden on December 29, 2022 as part of the Consolidated Appropriations Act, 2023 (H.R. 2617), includes numerous reforms to the accelerated approval process for drugs and biologics and enables the FDA to require, as appropriate, that a post-approval study be underway prior to granting accelerated approval. FDORA also expands the expedited withdrawal procedures

already available to the FDA to allow the agency to use expedited procedures if a sponsor fails to conduct any required post-approval study of the product with due diligence, including with respect to "conditions specified by the Secretary [of HHS]." FDORA also adds the failure of a sponsor of a product approved under accelerated approval to conduct with due diligence any required post-approval study with respect to such product or to submit timely reports with respect to such product to the list of prohibited acts in the FDCA.

Orphan Drug Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation, or ODD, to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200,000 individuals in the United States, or a patient population greater than 200,000 individuals in the United States and when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. ODD must be requested before submitting a BLA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has received ODD subsequently receives the first FDA approval for that drug for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the BLA user fee.

Post-approval Requirements

Biologics 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 complying with advertising and promotion requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. The FDA and other agencies actively enforce the laws and regulations applicable to biologics, including those 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. Promotional materials for approved biologics must be submitted to the FDA in conjunction with their first use or first publication.

After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There are also continuing annual program fees for any marketed products. Biologic manufacturers and their subcontractors are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMPs. 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 area of production and quality control to maintain compliance with cGMPs and other aspects of regulatory compliance.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events 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 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;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- fines, warning letters 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 license 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; and
- the imposition of civil or criminal penalties.

United States Biosimilars and Exclusivity

The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, signed into law in 2010, includes a subtitle called the Biologics Price Competition and Innovation Act, or BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. The FDA has issued several guidance documents outlining an approach to review and approval of biosimilars in the United States. Biosimilarity requires that there be no clinically meaningful differences between the biological product and the reference product in terms of safety, purity and potency. Interchangeability requires that a product is biosimilar to the reference product, and the product must demonstrate that it can be expected to produce the same clinical results as the reference product in any given patient and, for products that are administered multiple times to an individual, the biologic and the reference biologic may be alternated or switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference biologic.

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

The BPCIA is complex and continues to be interpreted and implemented by the FDA. In addition, government proposals have sought to reduce the 12-year reference product exclusivity period. Other aspects of the ACA, some of which may impact the BPCIA exclusivity provisions, have also been the subject of recent litigation. As a result, the ultimate impact, implementation and regulatory interpretation of the BPCIA remain subject to significant uncertainty.

Other Healthcare Laws

Pharmaceutical companies are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business, which may constrain their business operations, including financial arrangements related to the research, marketing and distribution of drug products. Such laws include, without limitation, the following, some of which may apply to our operations only if and when we have a marketed product:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate), directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly;
- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be

presented, to the federal government, claims for payment or approval that are false or fraudulent or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of services reimbursable to Medicare or a state health program, unless an exception applies;
- the federal Health Insurance Portability and Accountability Act, or HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for 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 the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, also imposes obligations on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," if those business associates create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as the business associates' covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the FDCA, which, among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws, such as the Medicaid Drug Rebate Program, 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 governmental healthcare programs;
- the so-called federal "sunshine law," or Open Payments, which requires manufacturers of drugs, devices, biologics and medical supplies to report to the CMS information related to payments and other transfers of value to teaching hospitals, physicians and other healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which 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 state laws which regulate interactions between pharmaceutical companies and healthcare providers, require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, require pharmaceutical companies to report information on transfers of value to other healthcare providers, marketing expenditures or pricing information and/or require licensing or registration of sales representatives.

Ensuring compliance with healthcare laws is time-consuming and costly. Given the breadth of the laws and regulations and narrowness of any exceptions, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity

agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

Coverage and Reimbursement

The ability of a pharmaceutical company to successfully commercialize and achieve market acceptance of a product depends in significant part on adequate coverage and reimbursement from third-party payors, including government healthcare programs, such as the Medicare and Medicaid programs, and private entities, such as managed care organizations and private health insurers.

In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors and coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved.

Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. To obtain or maintain coverage and reimbursement for any approved drug product, a pharmaceutical manufacturer may need to conduct expensive pharmacoeconomic studies or otherwise provide evidence to demonstrate the medical necessity and cost-effectiveness of a product. These studies will be in addition to the studies required to obtain or maintain regulatory approvals. If third-party payors do not consider a product to be cost-effective compared to other available therapies, the payors may not cover the product or, if they do, the level of payment may not be sufficient to allow sale of a product at a profit.

Even if third-party payors provide some coverage, they may impose limits on the coverage or controls to manage utilization of products. Third-party payors may limit coverage to specific products on an approved list, or formulary, which might not include all of the approved products for a particular indication and can exclude drugs from their formularies in favor of competitor drugs or alternative treatments. Payors may also impose step edits that require patients to try alternative, including generic, treatments before authorizing payment for our products, limit the types of diagnoses for which coverage will be provided, require pre-approval (known as "prior authorization") for coverage of a prescription for each patient (to allow the payor to assess medical necessity) or impose a moratorium on coverage for products while the payor makes a coverage decision.

Moreover, a third-party payor's decision to provide coverage for a product does not mean that an adequate reimbursement rate will be approved. A pharmaceutical company may be required to provide mandatory discounts or rebates to certain purchasers to obtain coverage under federal healthcare programs or to sell products to government purchasers. A pharmaceutical company may also have to offer discounts or rebates to private third-party payors to obtain favorable coverage. There has been significant consolidation in the health insurance industry, increasing the leverage of large insurers and pharmacy benefit managers in pricing and other negotiations and potentially impacting potential drug product sales, business and results of operations. Adequate third-party reimbursement may not be available to enable a company to realize an appropriate return on an investment in product development.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption or enhancement of price controls and cost-containment measures could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company receives regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory healthcare reform initiatives directed at broadening the availability of healthcare, improving the quality of

healthcare, and containing or lowering the cost of healthcare. These reform initiatives, if and when implemented, could impact our ability to sell a product candidate profitably if and when approved for marketing. For example, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; and established a Medicare Part D coverage gap discount program. More generally, the ACA expanded healthcare coverage through Medicaid expansion and the implementation of the "individual mandate" for health insurance coverage.

Beyond the ACA, there have been ongoing healthcare reform efforts, including efforts focused on drug pricing and payment. For example, the Inflation Reduction Act of 2022, or IRA, includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the previous ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with negotiated prices for the first set of drugs scheduled to take effect in 2026). The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Additionally, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap, and changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

More recently, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government offering pharmaceutical direct-to-consumer channels has also been launched. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of health care benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace, such as the elimination of certain subsidies, will increase the number of uninsured. Individual states in the United States have also become increasingly active in implementing 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.

Healthcare reform efforts have been and may continue to be subject to scrutiny, legal challenge and subsequent amendment, creating further uncertainty.

Other recent government actions may also affect prices or payments for prescription drugs. For example, the current presidential administration's recently announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act of 2011, as amended,

resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

Adoption of new legislation at the federal or state level could affect demand for, or pricing of, any future products if approved for sale. We cannot, however, predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results.

Employees and Human Capital Resources

Our human capital objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity incentive plans are to attract, retain and reward personnel through the granting of stock-based compensation awards.

As of March 25, 2026, we had 61 employees, 60 of which were full time. Of our 61 employees, 40 were engaged in research and development and 21 were engaged in general and administrative functions. We also utilized consultants in various roles related to research and development and general and administrative functions. We believe our employee relations are good.

Corporate Information

We were incorporated under the laws of the State of Delaware in 1996. Our principal executive offices are located at 1210-1220 Washington Street, Suite 210, Newton, MA 02465 and our telephone number is (617) 344-4190.

Available Information

Our website address is *http://www.acumenpharm.com/*. In addition to the information about us contained in this Annual Report on Form 10-K, information about us can be found on our website. Our website and information included in or linked to our website are not part of this Annual Report on Form 10-K.

Our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, are available free of charge through our website as soon as reasonably practicable after they are electronically filed with or furnished to the U.S. Securities and Exchange Commission, or the SEC. Additionally, the SEC maintains an internet site that contains reports, proxy and information statements and other information. The address of the SEC's website is *www.sec.gov*.

Item 1A. Risk Factors.

The following information sets forth risk factors that could cause our actual results to differ materially from those contained in forward-looking statements we have made in this Annual Report on Form 10-K and those we may make from time to time. You should carefully consider the risks described below, in addition to the other information contained in this Annual Report on Form 10-K and our other public filings. Our business, financial condition or results of operations could be harmed by any of these risks. The risks and uncertainties described below are not the only ones we face. Additional risks not presently known to us or other factors not perceived by us to present significant risks to our business at this time also may impair our business operations.

Risks Related to our Financial Position and Capital Needs

We are a clinical-stage biopharmaceutical company with a limited operating history.

We are a clinical-stage biopharmaceutical company with a limited operating history developing a novel disease-modifying approach targeting what we believe to be a key underlying cause of Alzheimer's disease, or AD. We were incorporated in 1996 and were party to an exclusive license and research collaboration with Merck & Co., Inc., or Merck, in 2003. Although we acquired the exclusive rights to sabirnetug from Merck in 2011, following Merck's strategic decision to focus its AD development efforts on a different product candidate, we did not recommence meaningful operations until we completed our first institutional fundraising in 2018. As a result, we have a limited operating history, which may make it difficult to evaluate the success of our business to date and to assess our future viability. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. We received authorization of our Investigational New Drug application, or IND, for our sole product candidate, sabirnetug, and initiated our Phase 1 clinical trial in the second quarter of 2021. In October 2021, we announced the initial dosing of the first patient in the INTERCEPT-AD trial and in February 2023 we announced the completion of enrollment. We announced topline data from INTERCEPT-AD in July 2023. We initiated our Phase 2 clinical trial, ALTITUDE-AD, in May 2024, completed enrollment in March 2025 and expect to announce top-line results in late 2026. We also conducted a Phase 1 clinical trial investigating a subcutaneous dosing option of sabirnetug in mid-2024 and announced results in March 2025. In addition, we announced a collaboration with JCR Pharmaceuticals Co. Ltd., or JCR, in July 2025, pursuant to which we are conducting preclinical studies, in coordination with JCR, to assess a blood-brain barrier-penetrating, Aß oligomer-targeted Enhanced Brain Delivery (EBD™) therapy for the treatment of AD. We have previously experienced delays in site activation and enrollment with respect to our INTERCEPT-AD clinical trial, and cannot assure you that we will not experience additional delays in site activation or enrollment in our future clinical trials. To date, we have not yet initiated a pivotal trial, obtained marketing approval for any product candidate, manufactured a commercial scale product candidate, arranged for a third party to do so on our behalf or conducted sales or marketing activities necessary for successful product candidate commercialization. Our short operating history makes any assessment of our future success and viability subject to significant uncertainty. We will likely encounter risks and difficulties frequently experienced by early-stage biopharmaceutical companies in rapidly evolving fields, and we have not yet demonstrated an ability to overcome such risks and difficulties successfully. If we do not address these risks and difficulties successfully, our business will suffer.

We have no product candidates approved for commercial sale, we have never generated any revenue from product sales and we may never be profitable.

We have no product candidates approved for sale, have never generated any revenue from product sales, have never been profitable and do not expect to be profitable in the foreseeable future. We have incurred net losses in each year since our inception. For the years ended December 31, 2025 and 2024, our net losses were $121.3 million and $102.3 million, respectively. As of December 31, 2025, we had an accumulated deficit of $446.5 million.

To date, we have devoted most of our financial resources to the research and development of sabirnetug, including our nonclinical development activities of sabirnetug and our clinical trials, and corporate overhead. We expect that it will be several years, if ever, before we have a product candidate approved and ready for commercialization. We expect to continue to incur losses for the foreseeable future, and we expect these losses to increase as we continue our development of, and seek regulatory approvals for, sabirnetug and any other product candidate we may develop in the future, prepare for and begin the commercialization of any approved product candidates and add infrastructure and personnel to support our drug development efforts and operations as a public company. We anticipate that any such losses could be significant for the next several years. These net losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Further, these net losses may fluctuate significantly from quarter-to-quarter or year-to-year. To become and remain profitable, we must develop and eventually commercialize sabirnetug or another drug with significant revenue.

We may never succeed in developing a commercial drug, and, even if we succeed in commercializing one or more product candidates, we may never generate revenues that are large enough to achieve profitability. In addition, we may encounter unforeseen expenses, difficulties, complications, delays and other known or unknown challenges. Because of these numerous risks and uncertainties, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to generate revenues or achieve profitability. If we do achieve profitability, we may not be able to sustain or increase profitability on a quarterly or annual basis, and we will continue to incur substantial research and development costs and other expenditures to develop and market additional product candidates.

We will require substantial additional funding to finance our operations, complete the development and commercialization of sabirnetug for AD and evaluate future product candidates, including any Aß oligomer-targeted EBD™ product candidates we may develop pursuant to our collaboration with JCR. If we are unable to raise additional funding when needed, we may be forced to delay, reduce or eliminate our drug development programs or other operations.

To date, we have used substantial amounts of cash to fund our operations, and we expect our expenses to increase substantially in the foreseeable future in connection with our ongoing activities, particularly as we continue the research and development, conduct clinical trials of, and seek marketing approval for, sabirnetug and any future product candidates we may develop. Developing sabirnetug and conducting clinical trials for the treatment of AD and any other product candidates or indications that we may pursue in the future will require substantial amounts of capital. In addition, if we obtain marketing approval for sabirnetug or any future product candidates, we expect to incur significant commercialization expenses related to the commercialization of the product, whether we are commercializing alone or with a collaborator. Further, we expect to incur significant expenses associated with operating as a public company.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. As of December 31, 2025, we had $54.0 million in cash and cash equivalents and $62.9 million in marketable securities. Based on our current operating plan, we believe that our existing cash and cash equivalents and marketable securities will be sufficient to enable us to fund our operating expenses and capital expenditure requirements into early 2027. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than anticipated if we choose to expand more rapidly than we presently anticipate.

The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- the progress, costs, timing and results of ALTITUDE-AD and other potential clinical trials of sabirnetug and/or preclinical trials related to the potential development of an Aß oligomer-targeted EBD™ therapy, or for any potential additional indications that we may pursue beyond AD;
- the requirements of the U.S. Food and Drug Administration, or FDA, and the European Medicines Agency, or EMA, and comparable foreign regulatory authorities, for clinical trials and nonclinical studies and other work, for review and approval of sabirnetug for AD;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- the number and characteristics of product candidates that we pursue;
- our ability to obtain sufficient quantities of our product candidates from our third-party manufacturers;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization capabilities if we were to elect to commercialize one or more products on our own;
- the economics and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter for the commercialization of our products;
- the costs and other terms, timing and success, of acquiring, in-licensing or investing in businesses, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;

- the effect of competing drugs and product candidates and other market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any funds we raise may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions. Additionally, escalation in interest rates may lead to financial institutions being more prudent with capital deployment and tightening lending. If we are unable to raise sufficient additional capital on a timely basis, we could be forced to curtail our planned operations and the pursuit of our business strategy, which would have a material adverse effect on the value of our common stock.

Our independent registered public accounting firm has included an explanatory paragraph relating to our ability to continue as a going concern in its report on our audited financial statements included in this Annual Report on Form 10-K.

The report from our independent registered public accounting firm for the year ended December 31, 2025 includes an explanatory paragraph stating that our recurring losses from operations raise substantial doubt about our ability to continue as a going concern for at least 12 months after the date of issuance of the financial statements included in this Annual Report on Form 10-K and we will need to obtain additional funding. See Note 1 to our financial statements appearing elsewhere in our Annual Report on Form 10-K for additional information on our assessment.

If we are unable to obtain sufficient funding to support our current operating plan, we may be forced to delay or reduce the scope of our product development programs, reduce our research and development costs, limit or cease our operations; our business, results of operations, financial condition and prospects may be adversely affected; and we may be unable to continue as a going concern. Our cash forecast contains estimates and assumptions related to our ongoing clinical trial and other research and development expenses, and we cannot predict the amount or timing of all expenditures with certainty. Nevertheless, our financial statements do not include any adjustments that might result from the outcome of this uncertainty.

We cannot guarantee that we will be able to obtain any or sufficient additional funding or that such funding, if available, will be obtainable on terms satisfactory to us. If we seek additional financing to fund our business activities in the future and there remains substantial doubt about our ability to continue as a going concern, investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our audited financial statements, and it is likely that investors will lose all or a part of their investment. There can be no assurance that the current operating plan will be achieved in the time frame anticipated by us, or that our cash resources will fund our operating plan for the period we anticipate.

The terms of our Loan Agreement place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our operating and financial flexibility.

In November 2023, we entered into the Loan Agreement with K2 HealthVentures LLC, or K2HV. At closing, we borrowed $30.0 million in the first tranche under the Loan Agreement. We may borrow an additional $20.0 million under the Loan Agreement upon our request, subject to review by the lenders of certain information from the Company and discretionary approval by the lenders.

Our obligations under the Loan Agreement are secured by a security interest in substantially all of our assets, excluding the Company's intellectual property. The Loan Agreement includes customary affirmative and negative covenants, as well as standard events of default, including an event of default based on the occurrence of a material adverse event. The negative covenants include, among others, restrictions on us transferring collateral, incurring additional indebtedness, engaging in mergers or acquisitions, paying cash dividends or making other distributions, making investments, creating liens, selling assets and making any payment on subordinated debt, in each case subject to certain exceptions. These restrictive covenants could limit our flexibility in operating our business and our ability to pursue business opportunities that we or our stockholders may consider beneficial. In addition, K2HV could declare a default upon the occurrence of any event that it interprets could have a material adverse effect, subject to the limitations specified in the Loan Agreement. Upon the

occurrence and continuance of an event of default, K2HV may declare all outstanding obligations immediately due and payable and take such other actions as set forth in the Loan Agreement. Any declaration of an event of default could significantly harm our business and prospects and could cause the price of our common stock to decline. If we are liquidated, the rights of our lenders to repayment would be senior to the rights of the holders of our common stock to receive any proceeds from the liquidation. We may not have enough available cash or be able to raise additional funds through equity or debt financings to repay these outstanding obligations at the time any event of default occurs. Further, if we raise any additional capital through debt financing, the terms of such additional debt could further restrict our operating and financial flexibility.

We are exposed to interest rate risk under our Loan Agreement with K2HV, which could cause our debt service obligations to increase significantly.

We are exposed to market risk from changes in interest rates. Under the Loan Agreement with K2HV, our term loan facility bears a variable interest rate equal to the greater of (i) 9.65% and (ii) the sum of (A) the prime rate last quoted in The Wall Street Journal and (B) 1.15%. An increase in interest rates by the Federal Reserve could cause the prime rate to increase, which could increase our debt service obligations. Significant increases in such obligations could have a negative impact on our financial position or operating results, including cash available for servicing our indebtedness, or result in increased borrowing costs in the future.

Risks Related to the Development of our Product Candidates

We are substantially dependent on the success of sabirnetug, our sole product candidate, which will require significant clinical testing before we can seek regulatory approval and potentially launch commercial sales, and which may not be successful in clinical trials, receive regulatory approval or be successfully commercialized, even if approved.

We are early in our development efforts. To date, we have invested substantially all of our efforts and financial resources in the research and development and clinical trials of sabirnetug, which is currently our only product candidate. Before seeking marketing approval from regulatory authorities for the sale of sabirnetug, or any other product candidate we may develop, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the drug in humans. We are not permitted to market or promote any product candidate before we receive regulatory approval from the FDA, or comparable foreign regulatory authorities, and we may never receive such regulatory approval. We cannot be certain that sabirnetug will be successful in clinical trials. Further, sabirnetug may not receive regulatory approval even if it is successful in clinical trials. If we do not receive regulatory approvals for sabirnetug, we may not be able to continue our operations. Our prospects, including our ability to finance our operations and generate revenue, will depend entirely on the successful development, regulatory approval and commercialization of sabirnetug by us or by one or more of our partners. The clinical and commercial success of sabirnetug will depend on a number of factors, including the following:

- successful completion of ALTITUDE-AD and other clinical trials of sabirnetug;
- sufficiency of our financial and other resources to complete the necessary clinical trials;
- the results from ALTITUDE-AD and future clinical trials of sabirnetug;
- the frequency and severity of adverse effects related to sabirnetug;
- the ability of third-party manufacturers to manufacture supplies of sabirnetug and to develop, validate and maintain a commercial-scale manufacturing process that is compliant with current good manufacturing practices, or cGMPs;
- our ability to demonstrate sabirnetug's safety and efficacy to the satisfaction of the FDA, EMA and any foreign regulatory authorities in order to receive necessary marketing approvals for sabirnetug;
- whether we are required by the FDA, EMA or other regulatory authorities to conduct additional clinical trials prior to the approval to market sabirnetug and whether the FDA, EMA or other regulatory authorities may disagree with the number, design, endpoints, size, conduct, implementation or other aspects of our clinical trials;
- whether the FDA, EMA or other regulatory authorities may require implementation of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition of approval or post-approval;
- our ability to successfully commercialize sabirnetug, if approved for marketing and sale by the FDA, EMA or foreign regulatory authorities, whether alone or in collaboration with others;
- our success in educating physicians and patients about the benefits, administration and use of sabirnetug;

- acceptance of sabirnetug as safe and effective by patients and the medical community;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments;
- our ability to achieve and maintain compliance with all regulatory requirements applicable to sabirnetug, including any required post-marketing approval commitments;
- effectively competing with other AD therapies;
- the effectiveness of our own or any future collaborators' marketing, pricing, coverage and reimbursement, sales and distribution strategies and operations;
- our ability to maintain our existing patents and obtain newly issued patents that cover sabirnetug and to enforce such patents and other intellectual property rights in and to sabirnetug;
- our ability to avoid third-party intellectual property claims;
- the availability of third-party coverage and adequate reimbursement for sabirnetug and any other product candidates, once approved; and
- a continued acceptable safety, tolerability and efficacy profile of sabirnetug following approval.

Many of these factors are beyond our control. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of sabirnetug. If we are not successful in commercializing sabirnetug, or are significantly delayed in doing so, our business will be materially harmed.

The FDA granted Fast Track designation for sabirnetug for the treatment of early AD, and we may seek Fast Track designation for other product candidates. Even if received, Fast Track designation may not actually lead to a faster review or approval process and does not increase the likelihood that our product candidates will receive marketing approval.

The FDA granted Fast Track designation for sabirnetug for the treatment of early AD in October 2022, and we may in the future seek Fast Track designation for any other product candidates we may develop. If a drug or biologic is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the sponsor may apply for FDA Fast Track designation for a particular indication. There is no assurance that the FDA will grant this status to any of our other product candidates. If granted, Fast Track designation makes a product eligible for more frequent interactions with FDA to discuss the development plan and clinical trial design, as well as rolling review of the application, which means that the company can submit completed sections of its marketing application for review prior to completion of the entire submission. Marketing applications of product candidates with Fast Track designation may qualify for priority review under the policies and procedures offered by the FDA, but the Fast Track designation does not assure any such qualification or ultimate marketing approval by the FDA. The FDA has broad discretion to decide whether to grant Fast Track designation, so even if we believe a particular product candidate is eligible for this designation, there can be no assurance that the FDA would decide to grant it. Even if we do receive Fast Track designation, we may not experience a faster development, review or approval process compared to conventional FDA procedures. In addition, the FDA may withdraw Fast Track designation at any time if it believes that the designation is no longer supported by data from our clinical development program.

We have concentrated our research and development efforts on the treatment of AD, a field that has to date seen very limited success in drug development.

We have focused our research and development efforts solely on developing effective treatments for AD. Collectively, efforts by pharmaceutical companies in the field of AD have seen limited successes in drug development. There are few approved products available for patients with AD.

Our future success is highly dependent on the successful development of sabirnetug for treating AD. The development and, if approved, commercialization of sabirnetug subjects us to a number of challenges, including ensuring that we select an effective dose and delivery mechanism of sabirnetug, executing appropriate clinical trials to test for safety and efficacy and obtaining regulatory approval from the FDA and other regulatory authorities. We cannot be sure that sabirnetug, or any other product candidate we develop, will ultimately prove to be safe and effective, scalable or profitable. Moreover, public perception of drug safety issues, including adoption of new therapeutics or novel approaches to treatment, may adversely influence the willingness of subjects to participate in clinical trials, or if approved, the willingness of physicians to prescribe novel treatments.

Our approach to the potential treatment of AD is based on a novel therapeutic approach, which exposes us to unforeseen risks.

There is no current scientific or general consensus on the causation of AD or method of action to treat AD. We have discovered and are developing sabirnetug, a humanized monoclonal antibody that selectively targets amyloid-beta oligomers, or AßOs, to treat AD. Our approach is based on research on AßOs, globular assemblies of the amyloid-beta, or Aß, peptide that are distinct from other forms of amyloid. AßOs have gained increasing scientific acceptance as a primary toxin involved in the initiation and propagation of AD pathology. Based on the results of our nonclinical studies to date and our INTERCEPT-AD Phase 1 clinical trial, we believe sabirnetug represents a differentiated approach from current and prior anti-Aß/plaque immunotherapies because of its selectivity for soluble AßOs. We believe that sabirnetug is the most advanced immunotherapy candidate in development that was designed to selectively target AßOs. However, we may ultimately discover that sabirnetug does not possess properties required for therapeutic effectiveness. We may spend substantial funds attempting to develop sabirnetug or other product candidates and never succeed in doing so.

The market for any products that we successfully develop, if any, will also depend on the cost of the product. We do not yet have sufficient information to reliably estimate what it would cost to commercially manufacture sabirnetug, and the actual cost to manufacture sabirnetug or any drug we develop in the future could materially and adversely affect the commercial viability of the drug. We may also find that the manufacture of our product candidates is more difficult than anticipated, resulting in an inability to produce a sufficient amount of our product candidates for our clinical trials or, if approved, commercial supply. If we do not successfully develop sabirnetug, or no other drug we develop with drug product can be reliably and economically manufactured at scale, we will not become profitable, which would materially and adversely affect the value of our common stock.

Nonclinical and clinical drug development involves a lengthy, expensive and uncertain process. The results of nonclinical studies and early clinical trials are not always predictive of future results. Sabirnetug or any other product candidate that we advance into clinical trials may not achieve favorable results in later clinical trials, if any, or receive marketing approval.

The research and development of product candidates is extremely risky. Only a small percentage of product candidates that enter the development process ever receive marketing approval. Before obtaining marketing approval from regulatory authorities for the sale of any product candidate, we must complete nonclinical development and then conduct extensive clinical trials to demonstrate the safety and efficacy of our product candidates in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain.

The results of nonclinical studies and early clinical trials are not necessarily predictive of future results and sabirnetug, or any other product candidate that we may develop, may not be further developed or have favorable results in later studies or trials. Clinical trial failure may result from a multitude of factors including, but not limited to, flaws in study design, dose selection, placebo effect, patient enrollment criteria and failure to demonstrate favorable safety or efficacy traits. As such, failure in clinical trials can occur at any stage of testing. Similarly, the results of INTERCEPT-AD may not be predictive of the results of outcomes in our later-stage clinical trials. The results of clinical trials in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen and other clinical trial protocols and the rate of dropout among clinical trial participants. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. This is particularly true in AD, where failure rates historically are higher than in most other disease areas.

In the event of negative or inconclusive results, we may decide, or regulatory authorities may require us, to conduct additional clinical trials or nonclinical studies. In addition, data obtained from clinical trials and nonclinical studies is susceptible to varying interpretations, and regulatory authorities may not interpret our data as favorably as we do, which may further delay, limit or prevent development efforts, clinical trials or marketing approval. Further, as more competing product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change.

If we are unable to complete nonclinical studies or clinical trials of sabirnetug or future product candidates, due to safety concerns or otherwise, or if the results of these trials are not sufficient to convince regulatory authorities of their safety or efficacy, we will not be able to obtain marketing approval for commercialization on a timely basis or at all. Even if we are able to obtain marketing approval for sabirnetug or any future product candidates, those approvals may be for indications

or dose levels that deviate from our desired approach or may contain other limitations that would adversely affect our ability to generate revenue from sales of those product candidates. Moreover, if we are not able to differentiate our product candidate against other approved product candidates within the same class of drugs, or if any of the other circumstances described above occur, our business would be harmed and our ability to generate revenue from that class of drugs would be severely impaired.

Clinical failure can occur at any stage of clinical development, and we have never submitted a biologics license application, or BLA, or other marketing authorization application, or MAA.

We are early in our development efforts for sabirnetug and will need to successfully complete our ongoing and planned clinical trials, including pivotal clinical trials, in order to obtain FDA approval to market sabirnetug or any other product candidate we seek to develop. Carrying out clinical trials and the submission of a successful BLA is a complicated process. Although members of the Acumen team have significant experience in clinical development of drugs through regulatory approval, as an organization, Acumen only recently completed its first clinical trial, has no previous experience in conducting any other clinical trials, has limited experience in preparing regulatory submissions and has not previously submitted a BLA for any product candidate.

In addition, although we have received important feedback on the design of ALTITUDE-AD from the FDA, we have had limited interactions with the FDA overall; similarly, based on regulatory feedback from the EMA and to enhance the probability that the EMA will consider our Phase 2 clinical trial a registration-eligible clinical trial for sabirnetug, we amended the ALTITUDE-AD protocol in 2024 to change from a Phase 2/3 clinical trial to a Phase 2 standalone clinical trial. However, we cannot be certain how many clinical trials of sabirnetug will be required or how such trials will be designed. Consequently, we may be unable to successfully and efficiently execute and complete necessary clinical trials in a way that leads to submission of a BLA or request for marketing authorization and approval of sabirnetug or any other product candidate. We may require more time and incur greater costs than our competitors and we may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our planned clinical trials, could prevent us from or delay us in commercializing sabirnetug or any future product candidates we may develop, and failure to successfully complete any of these activities in a timely manner could have a material adverse impact on our business and financial performance.

We may incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- regulatory authorities, Institutional Review Boards, or IRBs, or Ethics Committees, or ECs, may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site, or we may fail to reach a consensus with regulatory authorities on trial design; for example, our initial submission of the IND for sabirnetug was placed on clinical hold by the FDA until we were able to address the FDA's initial concerns regarding potential off-target binding of sabirnetug with an additional nonclinical tissue cross reactivity study, after which the FDA permitted us to initiate the Phase 1 clinical trial of sabirnetug in the second quarter of 2021;
- regulatory authorities in jurisdictions in which we seek to conduct clinical trials may have differing views on our trial design, and it may be difficult or impossible to satisfy all such authorities with one approach;
- we may have delays in reaching or fail to reach agreement on acceptable clinical trial contracts or clinical trial protocols with prospective trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different contract research organizations, or CROs, and trial sites;
- we may be unable to add or be delayed in adding a sufficient number of clinical trial sites and obtaining IRB or independent EC approval at each clinical trial site;
- clinical trials of our product candidates may fail to show safety or efficacy or otherwise produce negative or inconclusive results, and we may decide, or regulatory authorities may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate;
- enrollment in our clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;

- difficulties in having subjects complete a clinical trial or returning for post-treatment follow-up;
- changes to clinical trial protocols;
- our third-party contractors, including clinical investigators, contract manufacturers and vendors may fail to comply with applicable regulatory requirements, lose their licenses or permits, or otherwise fail to, or lose the ability to, meet their contractual obligations to us in a timely manner, or at all;
- we might have to suspend or terminate clinical trials of our product candidates for various reasons, including a finding that the participants are being exposed to unacceptable health risks;
- regulatory authorities or IRBs may require that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate, and we may lack adequate funding to initiate or continue one or more clinical trials;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- clinical trial sites may deviate from clinical trial protocol or drop out of a clinical trial;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies; and
- the policies, regulations, and guidelines of the FDA, EMA or other comparable foreign regulatory authorities regarding the development, approval and marketing of biologics may significantly change, which may hinder our development or commercialization of sabirnetug or future product candidates.

Adverse side effects, properties or other safety risks associated with sabirnetug or any future product candidates could delay or preclude approval, cause us to suspend or discontinue clinical trials, abandon further development, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

As is the case with pharmaceuticals generally, it is possible that there may be side effects and adverse events associated with the use of sabirnetug or any future product candidates we may develop. For example, with respect to our INTERCEPT-AD clinical trial, the most common treatment-emergent adverse events from all dose groups combined were ARIA-E (10.4%), ARIA-H (hemorrhage) (8.3%), COVID-19 (6.3%), and hypersensitivity (6.3%). The overall rate of ARIA-E was 10.4%, which included one case of symptomatic ARIA-E (2.1%). Results of ALTITUDE-AD, or future clinical trials, could reveal a high and unacceptable severity and prevalence of side effects or unexpected characteristics as the clinical trials progress to greater exposures and a larger number of patients. Undesirable side effects caused by, or unexpected or unacceptable characteristics associated with, sabirnetug or any future product candidates we may develop, could result in the delay, suspension or termination of clinical trials by us, the FDA or other comparable regulatory authorities, or IRBs for a number of reasons. We may also elect to limit their development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective, which may limit the commercial expectations for such product candidate, if approved. If we elect or are required to further delay, suspend or terminate any clinical trial of any product candidates we may develop, the commercial prospects of such product candidates will be harmed and our ability to generate drug revenues from any such product candidates will be delayed or eliminated.

It is possible that as we test sabirnetug in ALTITUDE-AD or future clinical trials, or as the use of sabirnetug becomes more widespread if it receives regulatory approval, we may identify additional adverse events that were not identified or not considered significant in our earlier trials. If such side effects, if any, become later known in development or upon approval, such findings may harm our business, financial condition, results of operations and prospects significantly. If we or others later identify undesirable side effects, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw, suspend or limit approval of sabirnetug or any future product candidates;
- we may be required to recall a drug or change the way such drug is administered to patients;
- regulatory authorities may require additional warnings or statements in the labeling, such as a boxed warning or a contraindication, or issue safety alerts, press releases or other communications containing warnings or other safety information about the product candidate, such as field alerts to physicians and pharmacies;

- regulatory authorities may require us to implement a REMS to ensure that the benefits of the drug outweigh its risks, which could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools;
- we may be required to change the way a drug is distributed or administered, conduct additional clinical trials or be required to conduct additional post-marketing studies or surveillance;
- we may be subject to regulatory investigations and government enforcement actions;
- we may decide to remove such product candidates from the market;
- personal injury claims, actions, lawsuits and proceedings that may arise from exposure to or taking our product candidates;
- sales of the drug may decrease significantly or sabirnetug or any future drug could become less competitive; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of sabirnetug or any future product candidates, if approved, and could significantly harm our business, financial condition, results of operations and prospects.

We have experienced and may continue to experience delays or difficulties in the enrollment and retention of patients in clinical trials, which could delay or prevent our receipt of necessary regulatory approvals.

Successful and timely completion of clinical trials will require that we enroll a sufficient number of patients. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and nature of the patient population and competition for patients eligible for our clinical trials with competitors which may have ongoing clinical trials for product candidates that are under development to treat the same indications as one or more of our product candidates or approved products for the conditions for which we are developing our product candidates.

Trials may be subject to delays as a result of patient enrollment taking longer than anticipated or patient withdrawal. We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or comparable foreign regulatory authorities. Throughout 2022, we experienced delays in clinical site initiation and patient enrollment that we believe were principally related to the effects of the COVID-19 pandemic. Although those enrollment delays were resolved, including through the addition of new clinical trial sites, and we did not experience enrollment delays with respect to our ALTITUDE-AD clinical trial, we may experience other enrollment delays in the future. We cannot predict how successful we will be at enrolling subjects in future clinical trials. Subject enrollment is affected by other factors including:

- the severity and difficulty of diagnosing the disease under investigation;
- the eligibility and exclusion criteria for the trial in question;
- the size of the patient population and process for identifying patients;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- the design of the trial protocol;
- the perceived risks and benefits of the product candidate in the trial, including relating to cell therapy approaches;
- the availability of competing commercially available therapies and other competing therapeutic candidates' clinical trials for the disease or condition under investigation;
- the willingness of patients to be enrolled in our clinical trials;
- the efforts to facilitate timely enrollment in clinical trials;
- the patient referral practices of physicians;
- the ability to monitor patients adequately during and after treatment; and
- the proximity and availability of clinical trial sites for prospective patients.

Our inability to enroll a sufficient number of patients for clinical trials would result in significant delays and could require us to abandon one or more clinical trials altogether. The enrollment delays we experienced in our INTERCEPT-AD clinical

trial resulted in increased development costs for the trial, including costs related to initiating additional trial sites, and any enrollment delays we may experience in future clinical trials of sabirnetug or any other product candidates we may develop may result in increased development costs for our product candidates, which would harm our business, financial condition and results of operations.

Further, we expect to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials and we will have limited influence over their performance. Additionally, even if we are able to enroll a sufficient number of patients for our clinical trials, we may have difficulty maintaining enrollment of such patients in our clinical trials.

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

From time to time, we may publish interim, topline or preliminary results from our clinical trials. Interim results from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Preliminary or topline results also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, interim and preliminary data should be viewed with caution until the final data are reported. Differences between preliminary, topline or interim data and final data could significantly harm our business prospects and may cause the trading price of our common stock to fluctuate significantly. 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 topline results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated.

Further, others, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular development program, the approvability or commercialization of the particular product candidate or product and our company in general. 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 the material or otherwise appropriate information to include in our disclosure. Any information we determine not to disclose may ultimately be deemed meaningful by you or others with respect to future decisions, conclusions, views, activities or otherwise regarding a particular product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, product candidates may be harmed, which could significantly harm our business prospects.

We cannot be certain that sabirnetug or any of our future product candidates will receive regulatory approval, and without regulatory approval we will not be able to market our product candidates.

We currently have no product candidates approved for sale and we cannot guarantee that we will ever have marketable product candidates. Sabirnetug is our sole product candidate and is designed for the treatment of AD. Our ability to generate revenue related to sales of sabirnetug, if ever, will depend on the successful development and regulatory approval of sabirnetug for the treatment of AD and, potentially, other indications.

The development of a product candidate and its approval and commercialization, including its design, testing, manufacture, safety, efficacy, recordkeeping, labeling, storage, approval, advertising, promotion, sale, distribution, import and export are subject to extensive regulation by the FDA, the EMA and comparable regulatory authorities in other countries, with regulations differing from country to country. We are not permitted to market our product candidates in the United States, Europe or other countries until we receive approval of a BLA from the FDA or MAA from the EMA, respectively. We have not submitted any marketing applications for sabirnetug.

BLAs and MAAs must include extensive nonclinical and clinical data and supporting information to establish the product candidate's safety and effectiveness for each desired indication. BLAs and MAAs must also include significant information regarding the chemistry, manufacturing and controls for the drug. Obtaining approval of a BLA or an MAA is a lengthy, expensive and uncertain process, and we may not be successful in obtaining approval. The FDA and the EMA review processes can take years to complete and approval is never guaranteed. If we submit a BLA to the FDA, the FDA must decide whether to accept or reject the submission for filing. We cannot be certain that any submissions will be accepted for

filing and review by the FDA. Regulators of other jurisdictions, such as the EMA, have their own procedures for approval of product candidates.

Even if a drug is approved, the FDA or the EMA, as the case may be, may limit the indications for which the drug may be marketed, require extensive warnings on the drug labeling or require expensive and time-consuming clinical trials or reporting as conditions of approval. Regulatory authorities in countries outside of the United States and Europe also have requirements for approval of product candidates with which we must comply prior with marketing in those countries. Obtaining regulatory approval for marketing of a product candidate in one country does not ensure that we will be able to obtain regulatory approval in any other country. In addition, delays in approvals or rejections of marketing applications in the United States, Europe or other countries may be based upon many factors, including regulatory requests for additional analyses, reports, data, nonclinical studies and clinical trials, regulatory questions regarding different interpretations of data and results, changes in regulatory policy during the period of drug development and the emergence of new information regarding sabirnetug or other product candidates we may develop in the future. Also, regulatory approval for any of our product candidates may be withdrawn.

Before we submit a BLA to the FDA or an MAA to the EMA for sabirnetug for the treatment of patients with AD, we will be required to successfully complete at least one pivotal clinical trial. The FDA and the EMA generally expect two pivotal clinical trials to support approval, although a single pivotal trial may be allowed in certain circumstances. In addition, we must scale up manufacturing and complete other standard nonclinical and clinical studies. We cannot predict whether our current or future trials will be successful or whether regulators will agree with our plans or conclusions regarding the nonclinical studies and the clinical trials we conduct.

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

We may in the future choose to conduct one or more of our clinical trials outside the United States, including in Europe. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA, EMA or applicable foreign regulatory authorities may be subject to certain conditions or may not be accepted at all. In cases where data from foreign clinical trials are intended to serve as the basis for marketing approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless (i) the data are applicable to the United States population and United States medical practice; and (ii) the trials were performed by clinical investigators of recognized competence and pursuant to current good clinical practice, or cGCP, regulations. Additionally, the FDA's clinical trial requirements, including sufficient size of patient populations and statistical powering, must be met. Many foreign regulatory bodies have similar approval requirements. In addition, such foreign trials would be subject to the applicable local laws of the foreign jurisdictions where the trials are conducted. There can be no assurance that the FDA, EMA or any other comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA, EMA or any applicable foreign regulatory authority does not accept such data, it would result in the need for additional trials, which would be costly and time-consuming and delay aspects of our business plan, and which may result in our product candidates not receiving approval or authorization for commercialization in the applicable jurisdiction.

We may not be successful in our efforts to build a pipeline of additional product candidates.

Our sole product candidate is sabirnetug. We may not be able to identify and successfully develop new product candidates in addition to sabirnetug. Even if we are successful in building our product pipeline, the potential product candidates that we identify may not be suitable for clinical development or, if deemed suitable for clinical development, may not be successful in any clinical trials. For example, product candidates may be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be successfully developed, much less receive marketing approval and achieve market acceptance. If we do not successfully develop and commercialize product candidates, we will not be able to obtain product revenue in future periods, which would result in significant harm to our financial position and adversely affect our stock price.

If we do not achieve our projected development goals in the time frames we announce and expect, the commercialization of our products may be delayed.

From time to time, we may estimate the timing of the accomplishment of various scientific, clinical, regulatory, manufacturing and other product development goals, which we sometimes refer to as milestones. These milestones may include the commencement or completion of nonclinical studies and clinical trials and the submission of regulatory filings, including BLA submissions. From time to time, we may publicly announce the expected timing of some of these milestones. All of these milestones are, and will be, based on a variety of assumptions. The actual timing of these

milestones can vary significantly compared to our estimates, in some cases for reasons beyond our control. We may experience numerous unforeseen events during, or as a result of, any future clinical trials that we conduct that could delay or prevent our ability to receive marketing approval or commercialize our product candidates.

We may develop sabirnetug and future product candidates for use in combination with other therapies, which could expose us to additional regulatory risks.

We may develop sabirnetug and future product candidates for use in combination with one or more other approved therapies for AD. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risk that the FDA or comparable foreign regulatory authorities could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially.

Further, we will not be able to market and sell any product candidate we develop in combination with an unapproved AD therapy for a combination indication if that unapproved therapy does not ultimately obtain marketing approval either alone or in combination with our product. In addition, unapproved AD therapies face the same risks described with respect to our product candidates currently in development and clinical trials, including the potential for serious adverse effects, delay in their clinical trials and lack of FDA approval.

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

As product candidates proceed through nonclinical studies to late-stage clinical trials toward potential approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods and formulation, are altered along the way in an effort to optimize processes and product characteristics. For example, through our contract manufacturing organizations, or CMOs, we plan to implement a larger scale sabirnetug manufacturing process with increased yields and at larger scale production levels. We are also developing a lyophilized drug product form and refrigeration-stable formulation.

Such changes carry the risk that they will not achieve our intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with the materials manufactured using altered processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commence sales and generate revenue. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of our future product candidates.

We face uncertainty regarding potential regulatory developments that may adversely affect our business.

We face uncertainty regarding the potential for changes in the regulatory environment applicable to biopharmaceutical companies in the United States. While many of the current presidential administration's policies appear to be focused on deregulation, the administration and federal government could adopt legislation, regulations or policies that adversely affect our business or create a more challenging and costly environment to pursue the development and commercialization of sabirnetug or any future product candidates we may develop. For example, the federal government, including the FDA, may implement legislative, regulatory or policy changes regarding the standards for approving biologic products that we may be unable to satisfy or regarding the marketing of approved biologics that may limit or prohibit the advertising and promotion of our current or future product candidates, if approved. Additionally, the current presidential administration has undertaken significant efforts to reduce the size and spending of the federal government, including through significant staff reductions of federal employees, which have impacted the FDA's workforce and may impact the FDA's ability to engage in routine regulatory and oversight activities and result in delays or limitations on our ability to proceed with clinical development programs and obtain regulatory approvals. It is difficult to predict how future executive actions that may be taken under the current presidential administration may affect the FDA's ability to exercise its regulatory authority. If such executive actions impose constraints on the FDA's ability to engage in routine oversight and product review activities in the normal course, our business may be negatively impacted.

Risks Related to the Commercialization of Our Product Candidates

Even if sabirnetug or any other product candidate we may develop receives marketing approval, it may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

If sabirnetug or any other product candidate we may develop receives marketing approval, it may nonetheless fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenue and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the clinical indications for which our product candidates are licensed;
- the efficacy, safety and potential advantages compared to alternative treatments;
- our ability to demonstrate the advantages of our product candidates over other medicines;
- our ability to offer our products for sale at competitive prices;
- the convenience and ease of administration compared to alternative treatments;
- product labeling or product insert requirements of the FDA or other comparable foreign regulatory authorities, including any limitations or warnings contained in a product's approved labeling, such as any black box warning or REMS;
- the willingness of the target patient population to try new treatments and of physicians to prescribe these treatments;
- our ability to commercialize the product either in collaboration with a third party or on our own;
- the timing of market introduction of our product candidates as well as competitive products;
- the strength of marketing and distribution support;
- the availability of third-party coverage and adequate reimbursement for sabirnetug and any other product candidates, once approved;
- the prevalence and severity of any side effects; and
- any restrictions on the use of our products together with other medications.

If we are unable to enter into a commercial collaboration or, alternatively, establish internal sales, marketing and distribution capabilities for sabirnetug or any other product candidate, including any Aβ oligomer-targeted EBD™ product candidates we may develop pursuant to our collaboration with JCR, that may receive regulatory approval, we may not be successful in commercializing those product candidates if and when they are approved.

We do not have a sales or marketing infrastructure. To achieve commercial success for sabirnetug or any other product for which we may obtain marketing approval, we will either need to establish a commercial collaboration with a pharmaceutical company that has a sales and marketing organization or we will be required to develop these capabilities internally. There are risks and limitations associated with entering into a commercial collaboration. For example, we may not be successful in entering into arrangements with third parties to sell, market and distribute our product candidates or may be unable to do so on terms that are favorable to us. Even if we are able to enter into a collaboration, our revenue and profitability, if any, are likely to be significantly lower than if we were able to successfully commercialize a product ourselves. In addition, we likely would have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively.

At the same time, there are significant risks associated with establishing our own sales, marketing and distribution capabilities. For example, recruiting and training a sales force is expensive and time-consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This would be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel.

Factors that may inhibit our efforts to market our products on our own include:

- our inability to recruit, train and retain adequate numbers of effective sales and marketing personnel;

- the inability of sales personnel to obtain access to physicians in order to educate physicians about our product candidates, once approved;
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating an independent sales and marketing organization.

If we do not establish sales, marketing and distribution capabilities successfully, either in collaboration with third parties or on our own, we will not be successful in commercializing our product candidates.

The affected populations for sabirnetug or any other product candidate we may develop may be smaller than we or third parties currently project, which may affect the addressable markets for our product candidates.

Our projections of the number of people who have AD, as well as the subset of people with AD who have the potential to benefit from treatment with sabirnetug, are estimates based on our knowledge and understanding of the disease. These estimates may prove to be incorrect and new studies may further reduce the estimated incidence or prevalence of the disease or narrow the universe of patients who would be expected to potentially benefit for treatment with sabirnetug, if approved. The number of patients in the United States, the European Union and elsewhere may turn out to be lower than expected, may not be otherwise amenable to treatment with our product candidates or patients may become increasingly difficult to identify and access, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain approval for sabirnetug, the FDA or other regulators may limit their approved indications to more narrow uses or subpopulations within the populations for which we are targeting development of sabirnetug.

The total addressable market opportunity for our product candidates will ultimately depend upon a number of factors, including the diagnosis and treatment criteria included in the final label, if approved for sale in specified indications, acceptance by the medical community, patient access and product pricing and reimbursement. Incidence and prevalence estimates are frequently based on information and assumptions that are not exact and may not be appropriate, and the methodology is forward-looking and speculative.

The estimated incidence and prevalence ranges included in this Annual Report on Form 10-K have been derived from data from multiple sources, including scientific literature, surveys of clinics, patient foundations or market research, and may prove to be incorrect. Accordingly, the incidence and prevalence estimates included in this Annual Report on Form 10-K should be viewed with caution. Further, the data and statistical information used in this Annual Report on Form 10-K, including estimates derived from them, may differ from information and estimates made by our competitors or from current or future studies conducted by independent sources.

Off-label use or misuse of our products may harm our reputation in the marketplace, result in injuries that lead to costly product liability suits, and subject us to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with any product.

If sabirnetug or any other product candidate we develop is approved by the FDA, we may only promote or market our product candidate for its specifically approved indications and consistent with its approved labeling. We or any third-party collaborator responsible for commercialization of our products will train the marketing and sales forces responsible for our products against promoting them for uses outside of their approved indications for use, known as “off-label uses.” However, neither we nor any future commercial partner of ours will be able to prevent a physician from using our products off-label, when in the physician’s independent professional medical judgment, he or she deems it appropriate. Further, the use of our products for indications other than those approved by the FDA may not effectively treat such conditions. Any such off-label use of our product candidates could harm our reputation in the marketplace among physicians and patients. There may also be an increased risk of injury to patients if physicians attempt to use our products for these uses for which they are not approved, which could lead to product liability suits that that might require significant financial and management resources and that could harm our reputation.

Advertising and promotion of any product candidate that obtains approval in the United States will be heavily scrutinized by the FDA, the U.S. Federal Trade Commission, or FTC, the Department of Justice, or DOJ, the Office of Inspector General of the U.S. Department of Health and Human Services, state attorneys general, members of the U.S. Congress and the public. Additionally, advertising and promotion of any product candidate that obtains approval outside of the United States will be heavily scrutinized by comparable foreign entities and stakeholders. Violations, including actual or alleged promotion of our products for unapproved or off-label uses, are subject to enforcement or warning letters, mandates to

issue corrective information to healthcare practitioners, inquiries, investigations, injunctions and civil and criminal sanctions by the FDA, DOJ or comparable foreign bodies. The federal government has levied large civil and criminal fines against companies for alleged improper promotion of off-label use and as enjoined several companies from engaging in an off-label promotion.

We may pursue Breakthrough Therapy designation by the FDA. This designation may not actually lead to a faster development or regulatory review or approval process, and it does not assure FDA approval of any product candidates we may develop.

The FDA's Breakthrough Therapy designation program is intended to expedite the development of certain qualifying products intended for the treatment of serious diseases and conditions. While we may seek Breakthrough Therapy designation, there is no guarantee that we will be successful in obtaining this designation. Even if we do obtain Breakthrough Therapy designation, we may not experience a faster development process, review or approval compared to conventional FDA procedures. Breakthrough Therapy designation alone does not guarantee qualification for the FDA's priority review procedures. A Breakthrough Therapy designation does not ensure that the product candidate will receive marketing approval or that approval will be granted within any particular timeframe. In addition, the FDA may withdraw Breakthrough Therapy designation if it believes that the designation is no longer supported by data from our clinical development program.

We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that our competitors may achieve regulatory approval before us or develop therapies that are safer or more effective than ours.

The development and commercialization of new drugs is highly competitive. Moreover, the AD field is characterized by strong competition and a strong emphasis on intellectual property. We may face competition with respect to any product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

If approved, sabirnetug will compete with therapies currently approved for the treatment of AD, which have primarily been developed to treat the symptoms of AD rather than the underlying cause of the disease, such as memantine and cholinesterase inhibitors. Sabirnetug may also compete with one or more potentially disease-modifying therapeutics that target Aß or amyloid plaques, including Eisai Co., Ltd.'s, or Eisai's, Leqembi (lecanemab), which was given full approval by the FDA in July 2023. Also in July 2023, Centers for Medicare and Medicaid Services, or CMS, announced it would cover Leqembi when a physician and care team participates in a CMS-facilitated registry. In August 2025, the FDA approved once-weekly subcutaneous maintenance dosing of Leqembi in patients with early AD following an 18-month intravenous induction period. Moreover, in January 2026, Eisai and Biogen Inc., or Biogen, announced that the FDA granted priority review for a subcutaneous starting dose of Leqembi with a Prescription Drug User Fee Act date of May 24, 2026. The FDA issued a complete response letter to Eli Lilly and Company, or Eli Lilly, in January 2023 for the accelerated approval submission of donanemab. In May 2023, Eli Lilly announced results from its donanemab Phase 3 TRAILBLAZER-ALZ 2 trial. In July 2024, the FDA approved donanemab.

Other companies known to be developing therapies with Aß-, AßO-, and amyloid plaque-related targets include AbbVie Inc., or Abbvie, Alector, Inc., or Alector, Alnylam Pharmaceuticals, Inc., AltPep Corporation, Alzheon, Inc., Alzinova AB, BioArctic AB, Biogen, Bristol-Myers Squibb Company, Cognition Therapeutics, Inc., Denali Therapeutics, Inc., or Denali, Eisai, Eli Lilly, Grifols, S.A., Korsana Biosciences, Inc., Neurimmune AG, Priavoid GmbH, ProMIS Neurosciences, Inc., Prothena Biosciences, Inc., Roche Holding AG (including Genentech, Inc., its wholly-owned subsidiary), or Roche, and Wavebreak Therapeutics, Inc. Additionally, sabirnetug, if approved, may also compete with other potential therapies intended to address underlying causes of AD that are being developed by several companies, including AbbVie, AC Immune SA, Alector, Anavex Life Sciences Corp., Annovis Bio, Inc., Biogen, Biohaven Pharmaceuticals, Inc., Cassava Sciences, Inc., Denali, Eisai, Johnson & Johnson (including Janssen Inc., its wholly-owned subsidiary), H. Lundbeck A/S, Lighthouse Pharmaceuticals, Inc., Roche, and Takeda Pharmaceutical Co. Ltd.

Many of our current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, nonclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved product candidates than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly

through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs. Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize product candidates that are safer, more effective, have fewer or less severe side effects, are more convenient, or are less expensive than any product candidates that we may develop. Further, currently approved product candidates could be discovered to have application for treatment of AD, which could give such product candidates significant regulatory and market timing advantages over any of our product candidates. Our competitors also may obtain FDA or other comparable regulatory approval for their product candidates more rapidly than we may obtain approval for ours from the FDA, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, product candidates or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors.

If our competitors market product candidates that are more effective, safer or less expensive than our product candidates, if approved, or that reach the market sooner than our product candidates, we may not achieve commercial success. In addition, the pharmaceutical industry is characterized by rapid technological change. If we fail to stay at the forefront of technological change, we may be unable to compete effectively. Technological advances or product candidates developed by our competitors may render our technologies or product candidates obsolete, less competitive or not economical.

Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated.

If we are successful in achieving regulatory approval to commercialize any biologic product candidate that we develop, such biologic product candidate may face competition from biosimilar products. In the United States, sabirnetug is, and we expect that any other product candidate we may seek to develop likely will be, regulated by the FDA as a biologic product subject to approval under the BLA pathway. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or, collectively, the ACA, includes a subtitle called the Biologics Price Competition and Innovation Act of 2009, or the BPCIA, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA-licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed by the FDA. During this 12-year period of exclusivity, another company may still market a competing version of the reference product if the FDA approves a full BLA for the competing product containing the sponsor's own nonclinical data and data from adequate and well-controlled clinical trials to demonstrate the safety, purity and potency of their product.

There is a risk that any of our product candidates approved as a biological product under a BLA would not qualify for the 12-year period of exclusivity or that this exclusivity could be shortened due to congressional action or otherwise, or that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for generic competition sooner than anticipated. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products will depend on a number of marketplace and regulatory factors that are still developing. If competitors are able to obtain marketing approval for biosimilars referencing our candidates, if approved, our products may become subject to competition from such biosimilars, with the attendant competitive pressure and potential adverse consequences.

The success of our product candidates will depend significantly on coverage and adequate reimbursement or the willingness of patients to pay for these therapies.

We believe our success depends on obtaining and maintaining coverage and adequate reimbursement from third-party payors for sabirnetug and any other product candidate we successfully develop, and the extent to which patients will be willing to pay out-of-pocket for such products, in the absence of reimbursement for all or part of the cost. In the United States and in other countries, patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. The availability of coverage and adequacy of reimbursement for our products by third-party payors, including government healthcare programs (e.g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations and other organizations are essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates.

Third-party payors determine which products and procedures they will cover and establish reimbursement levels. Coverage may be more limited than the approved indication in the label; provided only if the specific conditions are met; or subject to measures to control utilization (such as a prior approval process for coverage). One payor's determination to provide coverage for a drug product does not assure that other payors will also provide coverage. Even if a third-party payor covers a particular product or procedure, the resulting reimbursement payment rates may not be adequate. Patients who are treated in-office for a medical condition generally rely on third-party payors to reimburse all or part of the costs associated with the procedure, including costs associated with products used during the procedure, and may be unwilling to undergo such procedures in the absence of such coverage and adequate reimbursement. Physicians may be unlikely to offer procedures for such treatment if they are not covered by insurance and may be unlikely to purchase and use our product candidates, if approved, for our stated indications unless coverage is provided and reimbursement is adequate. In addition, for products administered under the supervision of a physician, obtaining coverage and adequate reimbursement may be particularly difficult because of the higher prices often associated with such drugs.

Reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that a procedure is safe, effective and medically necessary; appropriate for the specific patient; cost-effective; supported by peer-reviewed medical journals; included in clinical practice guidelines; and neither cosmetic, experimental nor investigational. Further, increasing efforts by third-party payors to limit healthcare costs may cause such payors to limit both coverage and the level of reimbursement for newly approved products and, as a result, payors may not cover or provide adequate payment for our product candidates. In order to secure coverage and reimbursement for any product that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of our products, in addition to the costs required to obtain FDA or comparable regulatory approvals. Additionally, we may also need to provide discounts to purchasers, private health plans or government healthcare programs. Our product candidates may nonetheless not be considered medically necessary or cost-effective. If third-party payors do not consider a product to be cost-effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit. We expect to experience pricing pressures from third-party payors in connection with the potential sale of any of our product candidates.

Decreases in third-party reimbursement for any product or a decision by a third-party payor not to cover a product could reduce physician usage and patient demand for the product and also have a material adverse effect on sales.

Foreign governments also have their own healthcare reimbursement systems, which vary significantly by country and region, and we cannot be sure that coverage and adequate reimbursement will be made available with respect to the treatments in which our products are used under any foreign reimbursement system.

There can be no assurance that sabirnetug or any other product candidate, if approved for sale in the United States or in other countries, will be considered medically reasonable and necessary, that the product candidate will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not adversely affect our ability to sell our product candidates profitably, if they are approved for sale.

Product liability lawsuits against us could cause us to incur substantial liabilities and to limit commercialization of any products that we may develop.

We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any products that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or drugs caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for any product candidates or drugs that we may develop;
- injury to our reputation and significant negative media attention;
- withdrawal of clinical trial participants;
- significant costs to defend the related litigation;
- substantial monetary awards paid to trial participants or patients;
- loss of revenue;
- reduced resources of our management to pursue our business strategy; and

- the inability to commercialize any products that we may develop.

Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of our product candidates. Insurance coverage is increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise.

We are subject to a variety of privacy and data security laws, and our failure to comply with them could harm our business.

We maintain a large quantity of sensitive information, including confidential business and personal information in connection with the conduct of our clinical trials and related to our employees, and we are subject to laws and regulations governing the privacy and security of such information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues, which may affect our business and is expected to increase our compliance costs and exposure to liability. In the United States, numerous federal and state laws and regulations could apply to our operations or the operations of our partners, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws and regulations (e.g., Section 5 of the FTC Act), that govern the collection, use, disclosure and protection of health-related and other personal information. In addition, we may obtain health information from third parties (including research institutions from which we obtain clinical trial data) that are subject to privacy and security requirements under the Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act and regulations promulgated thereunder. Depending on the facts and circumstances, we could be subject to significant penalties if we obtain, use or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA. In some states, such as California and Washington, state privacy laws are even more protective than HIPAA.

Congress has also enacted the Protecting Americans' Data from Foreign Adversaries Act of 2024, which establishes new restrictions on transfers of certain personally identifiable sensitive data to foreign adversary countries and entities controlled by a foreign adversary. Similarly, U.S. Department of Justice "Data Security Program" regulations issued pursuant to Executive Order 14117, "Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern," may restrict, and in some cases prohibits, data transfers involving countries of concern or covered persons, including the People's Republic of China (including Hong Kong and Macau), Russia, Iran, North Korea, Cuba and Venezuela that involve certain U.S. government-related data and bulk human 'omic, geolocation, biometric, health, financial, and other sensitive personal data. The Data Security Program applies even to data that have been de-identified, anonymized or encrypted. Entities organized under the laws of the United States as well as U.S. persons are restricted in their ability to provide access to such data to such countries as well as "covered persons" that have certain nexuses to such countries, and they are also required to prohibit foreign parties from making an "onward transfer" of such data to countries of concern and covered persons. These restrictions may inhibit or preclude our ability to fully realize the value of such data, to use such data effectively or efficiently, or to engage in some data transactions that would otherwise be available to entities not subject to the Data Security Program.

In addition, states are adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. Approximately 20 states have now passed comprehensive privacy laws that have taken effect or will come into effect at various times over the next few years. Similar laws have been passed or are being considered in several other states, as well as at the federal and local levels. The evolving patchwork of differing state and federal privacy and data security laws may increase the cost and complexity of operating our business and could increase our exposure to liability. We will continue to monitor and assess the impact of these state laws, which may impose substantial penalties for violations, impose significant costs for investigations and compliance, and carry significant potential liability for our business.

Outside of the United States, data protection and information security laws, including the E.U. General Data Protection Regulation, or the EU GDPR, which also forms part of the law of England and Wales, Scotland and Northern Ireland by virtue of section 3 of the European Union (Withdrawal) Act 2018 and as amended by the Data Protection, Privacy and Electronic Communications (Amendments etc.) (EU Exit) Regulations 2019 (SI 2019/419), or the UK GDPR, also apply to certain of our operations. The EU GDPR and the UK GDPR impose, among other things, data protection requirements that include strict obligations and restrictions on the ability to collect, analyze and transfer personal data of individuals within the EU and UK, a requirement for prompt notice of data breaches to data subjects and supervisory authorities in certain circumstances, and possible substantial fines for any violations. Companies that must comply with the EU GDPR and the

UK GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million (or £17.5 million under the UK GDPR) or 4% of the annual global revenues of the noncompliant company, whichever is greater. The EU GDPR and UK GDPR also impose additional restrictions and obligations in relation to the processing of sensitive categories of personal data, including health data. Moreover, on June 19, 2025 the UK's Data (Use and Access) Act took effect, which introduces certain amendments to the data protection regime in the UK, and therefore creates divergences between the EU and UK. Other governmental authorities around the world are considering and, in some cases, have enacted, similar privacy and data security laws. Failure to comply with applicable data protection laws and regulations could result in government investigations and/or enforcement actions (which could include substantial civil and/or criminal penalties), private litigation and adverse publicity and could negatively affect our business, financial condition and results of operations.

Although we work to comply with applicable laws and regulations relating to data privacy and security, these requirements are evolving and may be modified, interpreted and applied in an inconsistent manner from one jurisdiction to another and may conflict with one another or other legal obligations with which we must comply. Monitoring, preparing for and complying with the array of privacy and security legal regimes to which we are subject also requires us to devote significant resources, including, without limitation, financial and time-related resources. Moreover, many of the laws and regulations in this area are relatively new and their interpretations are uncertain and subject to change. Combined with the frequency with which new privacy and security laws are introduced globally, this means that we may be required to make changes to our operations or practices in an effort to comply with them. Such changes may increase our operating costs. We may also face inconsistent legal requirements across the various jurisdictions in which we operate, further raising both costs of compliance and likelihood that we will fail to satisfy all of our legal requirements. Any failure or perceived failure by us or our employees, representatives, contractors, consultants, collaborators, or other third parties to comply with such requirements or adequately address privacy and security concerns, even if unfounded, could result in additional cost and liability to us, damage our reputation, and adversely affect our business and results of operations.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health, and safety laws and regulations, we could become subject to fines or penalties or incur costs that could seriously harm our business.

We and any contract manufacturers and suppliers we engage are subject to numerous federal, state and local environmental, health and safety laws, regulations and permitting requirements, including those governing laboratory procedures; the generation, handling, use, storage, treatment and disposal of hazardous and regulated materials and wastes; the emission and discharge of hazardous materials into the ground, air and water; and employee health and safety. Our operations involve the use of hazardous and flammable materials, including chemicals and biological materials. Our operations also produce hazardous waste. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials. In the event of contamination or injury resulting from our use of hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. Under certain environmental laws, we could be held responsible for costs relating to any contamination at our current or past facilities and at third-party facilities. We also could incur significant costs associated with civil or criminal fines and penalties.

Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our research, product development and manufacturing efforts. In addition, we cannot entirely eliminate the risk of accidental injury or contamination from these materials or wastes. Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological or hazardous waste insurance coverage, and our property, casualty and general liability insurance policies specifically exclude coverage for damages and fines arising from biological or hazardous waste exposure or contamination. Accordingly, in the event of contamination or injury, we could be held liable for damages or be penalized with fines in an amount exceeding our resources, and our clinical trials or regulatory approvals could be suspended, which could seriously harm our business.

Risks Related to Our Dependence on Third Parties

We currently rely on CMOs to supply components of and manufacture sabirnetug. The loss of any of these CMOs or the failure of any of them to meet their obligations to us could affect our ability to develop sabirnetug in a timely manner.

We do not own or operate manufacturing facilities and rely on a limited number of CMOs to manufacture our product candidates. We have entered into agreements with third-party CMOs to manufacture sabirnetug and supply our clinical trial material, in compliance with applicable regulatory and quality standards. We intend to continue to rely on third-party

CMOs to manufacture our clinical supply for the foreseeable future. Any replacement of a third-party CMO could require significant effort, expense and expertise because there may be a limited number of qualified replacements. Any delays in obtaining adequate clinical supply that meets the necessary quality standards may delay our development or commercialization.

Our reliance on CMOs for manufacturing activities will reduce our control over these activities but will not relieve us of our responsibility to ensure compliance with all required regulations. Under certain circumstances, these CMOs may be entitled to terminate their engagements with us. If a CMO terminates its engagement with us, or does not successfully carry out its contractual duties, meet expected deadlines or manufacture sabirnetug or any other product candidate that we develop in accordance with regulatory requirements, or if there are disagreements between us and a CMO, we may not be able to complete, or may be delayed in completing, the clinical trials required for approval of sabirnetug or any other product candidate. In such instance, we may need to enter into an appropriate replacement third-party relationship, which may not be readily available or available on acceptable terms, which would cause additional delay or increased expense prior to the approval of sabirnetug or any future product candidate and would thereby have a negative impact on our business, financial condition, results of operations and prospects.

We may rely on additional third parties to manufacture ingredients of our product candidates in the future and to perform quality testing. Reliance on CMOs and other third-party service providers entails risks to which we would not be subject if we manufactured the product candidates ourselves, including:

- reduced control for certain aspects of manufacturing activities;
- termination or nonrenewal of the applicable manufacturing and service agreements in a manner or at a time that is costly or damaging to us;
- the possible breach by our third-party manufacturers and service providers of our agreements with them;
- the failure of our third-party manufacturers and service providers to comply with applicable regulatory requirements;
- disruptions to the operations of our third-party manufacturers and service providers caused by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or service provider; and
- the possible misappropriation of our proprietary information, including our trade secrets and know-how.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, impact our ability to successfully commercialize any of our product candidates or otherwise harm our business, financial condition, results of operations, stock price and prospects. Some of these events could be the basis for FDA or other comparable regulatory authority action, including injunction, recall, seizure or total or partial suspension of product manufacture.

We intend to rely on CROs and other third parties to conduct, supervise and monitor a significant portion of our research and nonclinical testing and clinical trials for sabirnetug or any future product candidates, and if those third parties do not successfully carry out their contractual duties, comply with regulatory requirements or otherwise perform satisfactorily, we may not be able to obtain regulatory approval or commercialize our product candidates, or such approval or commercialization may be delayed, and our business may be substantially harmed.

We engage, and intend to continue to engage, CROs and other third parties to conduct our nonclinical studies and clinical trials, including ALTITUDE-AD and any future clinical trials of sabirnetug we may pursue, and to monitor and manage data. We expect to continue to rely on third parties, including clinical data management organizations, medical institutions and clinical investigators, in the future. Any of these third parties may terminate their engagements with us in accordance with the applicable contract, whether in the event of an uncured material breach or at any time for convenience. If any of our relationships with these third parties terminate, we may not be able to timely enter into arrangements with alternative third parties or to do so on commercially reasonable terms, if at all. Switching or adding CROs involves substantial cost and requires management's time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines. Though we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, financial condition and prospects.

In addition, any third parties conducting our clinical trials will not be our employees, and except for remedies available to us under our agreements with such third parties, we cannot control whether they devote sufficient time and resources to our clinical programs. If these third parties do not successfully carry out their contractual duties or obligations or meet expected

deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. Consequently, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase substantially and our ability to generate revenue could be delayed significantly.

We rely on these parties for execution of our nonclinical studies and clinical trials and generally do not control their activities. Our reliance on these third parties for research and development activities will reduce our control over these activities but will not relieve us of our responsibilities. For example, we will remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires us to comply with cGCPs, which are standards 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. If we or any of our CROs or other third parties, including trial sites, fail to comply with applicable cGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA, EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure you that upon inspection by a given regulatory authority, such regulatory authority will determine that any of our clinical trials complies with cGCP regulations. In addition, our clinical trials must be conducted with product produced under cGMP conditions. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process, or may result in fines, adverse publicity and civil and criminal sanctions.

We also are required to register certain ongoing clinical trials and post the results of certain completed clinical trials on a government-sponsored database, ClinicalTrials.gov, within specified timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions.

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. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA 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 and may ultimately lead to the denial of marketing approval for sabirnetug or any other product candidate we develop.

We also expect to rely on other third parties to store and distribute product supplies for our clinical trials. Any performance failure on the part of our distributors could delay clinical development or marketing approval of our product candidates or commercialization of our products, producing additional losses and depriving us of potential revenue.

If any of our third-party manufacturers encounter difficulties in production of sabirnetug or any future product candidate we develop, or fail to meet rigorously enforced regulatory standards, our ability to provide supply of our product candidates for clinical trials or, if approved, for commercial sale could be delayed or stopped, or we may be unable to maintain a commercially viable cost structure.

The processes involved in manufacturing sabirnetug and any other product candidate we may develop are highly regulated and subject to multiple risks. As product candidates are developed through nonclinical studies to late-stage clinical trials towards approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, are altered along the way in an effort to optimize processes and results. Such changes carry the risk that they will not achieve these intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials. When changes are made to the manufacturing process, we may be required to provide preclinical and clinical data showing the comparable identity, strength, quality, purity or potency of the products before and after such changes. If microbial, viral or other contaminations are discovered at the facilities of our third-party manufacturers, such facilities may need to be closed for an extended period of time to investigate and remedy the contamination, which could delay clinical trials and adversely harm our business.

In order to conduct clinical trials of our product candidates, or supply commercial product candidates, if approved, we will need to manufacture them in both small and large quantities. We currently rely on third parties to manufacture sabirnetug for clinical trial purposes, and our manufacturing partners will have to modify and scale-up the manufacturing process when we transition to commercialization of our product candidates. Our manufacturing partners may be unable to successfully modify or scale-up the manufacturing capacity for any of our product candidates in a timely or cost-effective

manner, or at all. In addition, quality issues may arise during scale-up activities. If our manufacturing partners are unable to successfully scale-up the manufacture of our product candidates in sufficient quality and quantity, the development, testing and clinical trials of that product candidate may be delayed or become infeasible, and regulatory approval or commercial launch of any resulting product may be delayed or not obtained, which could significantly harm our business. The same risks would apply to our internal manufacturing facilities, should we in the future decide to build internal manufacturing capacity. In addition, building internal manufacturing capacity would carry significant risks in terms of being able to plan, design and execute on a complex project to build manufacturing facilities in a timely and cost-efficient manner.

In addition, the manufacturing process for any product candidates that we may develop is subject to FDA, EMA and foreign regulatory requirements and continuous oversight, and we will need to contract with manufacturers who can meet all applicable FDA, EMA and comparable foreign regulatory authority requirements, including complying with cGMPs on an ongoing basis. If we or our third-party manufacturers are unable to reliably produce product candidates in accordance with the requirements of the FDA, EMA or other regulatory authorities, we may not obtain or maintain the approvals we need to commercialize such product candidates. Even if we obtain regulatory approval for any of our product candidates, there is no assurance that either we or our third-party contract manufacturers will be able to manufacture the approved product in accordance with the requirements of the FDA, EMA or other comparable regulatory authorities, to produce it in sufficient quantities to meet the requirements for the potential launch of the product, or to meet potential future demand. Any of these challenges could delay completion of clinical trials, require bridging clinical trials or the repetition of one or more clinical trials, increase clinical trial costs, delay approval of our product candidate, impair commercialization efforts, increase our cost of goods and have an adverse effect on our business, financial condition, results of operations and growth prospects. Significant non-compliance could also result in the imposition of sanctions, including warning or untitled letters, fines, injunctions, civil penalties, failure of regulatory authorities to grant marketing approvals for our product candidates, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of products, operating restrictions and criminal prosecutions, any of which could damage our reputation and our business.

We will likely seek collaborations with third parties for the development and commercialization of sabirnetug or any future product candidates. If those collaborations are not successful, we may not be able to capitalize on the market potential of those product candidates, including sabirnetug.

We will likely seek third-party collaborators for the development and commercialization of sabirnetug and any of our future product candidates in the United States and may enter into collaboration agreements for the development and commercialization of any of our product candidates outside the United States. In the United States, commercialization partners are likely to include large biotechnology or pharmaceutical companies. Our likely collaborators outside the United States would most likely include regional and national pharmaceutical companies and biotechnology companies. If we enter into such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements.

Collaborations involving our product candidates would pose the following risks to us:

- collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations;
- collaborators may not perform their obligations as expected;
- collaborators may not pursue development and commercialization of any product candidates that achieve regulatory approval or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborators' strategic focus or available funding, or external factors, such as an acquisition, that divert resources or create competing priorities;
- collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive than ours;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;

- product candidates discovered in collaboration with us may be viewed by our collaborators as competitive with their own product candidates or drugs, which may cause collaborators to cease to devote resources to the commercialization of our product candidates;
- a collaborator with marketing and distribution rights to one or more of our product candidates that achieve regulatory approval may not commit sufficient resources to the marketing and distribution of such products;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the preferred course of development, might cause delays or termination of the research, development or commercialization of product candidates, might lead to additional responsibilities for us with respect to product candidates, or might result in litigation or arbitration, any of which would be time-consuming and expensive;
- collaborators may not properly maintain or defend our or their intellectual property rights or may use our or their proprietary information in such a way as to invite litigation that could jeopardize or invalidate such intellectual property or proprietary information or expose us to potential litigation;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; and
- collaborations may be terminated for the convenience of the collaborator and, if terminated, we could be required to raise additional capital to pursue further development or commercialization of the applicable product candidates.

Collaboration agreements may not lead to development or commercialization of product candidates in the most efficient manner or at all. If any future collaborator of ours were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program could be delayed, diminished or terminated.

We face significant competition in seeking appropriate collaborators. Whether we reach a definitive agreement for any collaboration will depend, among other things, upon our assessment of the collaborator's resources and expertise, the terms and conditions of the proposed collaboration and the proposed collaborator's evaluation of a number of factors. Those factors may include the design or results of clinical trials, the likelihood of approval by the FDA, EMA or similar regulatory authorities outside the United States, the potential market for the subject product candidate, the costs and complexities of manufacturing and delivering such product candidate to patients, the potential of competing products, the existence of uncertainty with respect to our ownership of technology, which can exist if there is a challenge to such ownership without regard to the merits of the challenge, and industry and market conditions generally. The collaborator may also consider alternative product candidates or technologies for similar indications that may be available to collaborate on and whether such a collaboration could be more attractive than the one with us for our product candidate. Collaborations are complex and time-consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators.

We may not be able to negotiate additional collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of such product candidate, reduce or delay its development program or one or more of our other development programs, delay its potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidates or bring them to market and generate revenue.

We may be exposed to a variety of international risks that could materially adversely affect our business.

We may enter into agreements with third parties for the development and commercialization of product candidates in international markets. International business relationships will subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- differing regulatory requirements for product approvals internationally;
- potentially reduced protection for intellectual property rights;
- potential third-party patent rights in countries outside of the United States;

- the potential for so-called "parallel importing," which is what occurs when a local seller, faced with relatively high local prices, opts to import goods from another jurisdiction with relatively low prices, rather than buying them locally;
- pricing pressure and differing reimbursement regimes:
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability, particularly in non-U.S. economies and markets;
- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- taxes in other countries;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, such as the ongoing wars in Ukraine and Iran and the Israel-Hamas war, or natural disasters, including earthquakes, volcanoes, typhoons, pandemics, epidemics, floods, hurricanes and fires.

If we engage in acquisitions, we will incur a variety of costs and we may never realize the anticipated benefits of such acquisitions.

Although we currently have no plans to do so, we may attempt to acquire businesses, technologies or drug candidates that we believe are a strategic fit with our business. If we do undertake any acquisitions, the process of integrating an acquired business, technology or drug candidates into our business may result in unforeseen operating difficulties and expenditures, including diversion of resources and management's attention from our core business. In addition, we may fail to retain key executives and employees of the companies we acquire, which may reduce the value of the acquisition or give rise to additional integration costs. Future acquisitions could result in additional issuances of equity securities that would dilute the ownership of existing stockholders.

Future acquisitions could also result in the incurrence of debt, contingent liabilities or the amortization of expenses related to other intangible assets, any of which could adversely affect our operating results. In addition, we may fail to realize the anticipated benefits or synergies of any acquisition.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient intellectual property protection for sabirnetug and any future product candidates, including any Aß oligomer-targeted EBD™ product candidates, as well as any other proprietary technologies we develop, or if the scope of the intellectual property protection obtained is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize our product candidate, and other proprietary technologies if approved, may be adversely affected.

Our commercial success will depend in part on our ability to obtain and maintain a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our product candidate, and other proprietary technologies we may develop. If we are unable to obtain or maintain patent protection with respect to our product candidate and any other proprietary technologies we may develop, our business, financial condition, results of operations and prospects could be materially harmed.

The patent position of biotechnology and pharmaceutical companies is highly uncertain and involves complex legal, scientific and factual questions and has been the subject of frequent litigation in recent years. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our patent applications may not result in patents being issued that protect our product candidate and other proprietary technologies we may develop or that effectively prevent others from commercializing competitive technologies and products. Further, no consistent policy regarding the breadth of claims allowed in pharmaceutical patents has emerged to date in the United States or in many jurisdictions outside of the United States. Changes in either the patent laws or interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth

of claims that may be enforced in the patents that may be issued from the applications we may own or license from third parties. Further, if any patents we obtain or license are deemed invalid and unenforceable, our ability to commercialize or license our technology could be adversely affected.

The patent application process is subject to numerous risks and uncertainties, and there can be no assurance that we or any of our actual or potential future collaborators will be successful in protecting our product candidate and other proprietary technologies and their uses by obtaining, defending and enforcing patents. These risks and uncertainties include the following:

- the United States Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process, the noncompliance with which can result in abandonment or lapse of a patent or patent application, and partial or complete loss of patent rights in the relevant jurisdiction;
- patent applications may not result in any patents being issued;
- issued patents may be challenged, invalidated, modified, revoked, circumvented, found to be unenforceable or may otherwise not provide any competitive advantage;
- our competitors, many of whom have substantially greater resources than we do and many of whom have made significant investments in competing technologies, may seek or may have already obtained patents that will limit, interfere with, or eliminate our ability to make, use and sell our product candidate;
- other parties may have designed around our claims or developed technologies that may be related or competitive to ours, may have filed or may file patent applications and may have received or may receive patents that overlap or conflict with our patent applications and/or patents, either by claiming the same composition of matter, methods or formulations or by claiming subject matter that could dominate our patent position;
- any successful opposition to any patents owned by or licensed to us could deprive us of rights necessary for the practice of our technologies or the successful commercialization of any product candidate that we may develop;
- because patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain that we or our licensors were the first to file any patent application related to our product candidate and other proprietary technologies and their uses;
- an interference proceeding can be initiated by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of any application with an effective filing date before March 16, 2013;
- there may be significant pressure on the U.S. 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; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop and market competing product candidate in those countries.

The patent prosecution process is expensive, time-consuming and complex, and we may not be able to file, prosecute or maintain all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. Although we enter into a non-disclosure and confidentiality agreement with parties who have access to patentable aspects of our research and development output, such as our employees, corporate collaborators, outside scientific collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach such agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection for such output. In addition, our ability to obtain and maintain valid and enforceable patents depends on whether the differences between our inventions and the prior art allow our inventions to be patentable over the prior art. Further, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. If we do not adequately protect our intellectual property and proprietary technology, competitors may be able to use our product candidate and other proprietary technologies and erode or negate any competitive advantage we may have, which could have a material adverse effect on our financial condition and results of operations. For example:

- others may be able to make compounds that are similar to our product candidate but that are not covered by the claims of our patents;
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- any patents that we obtain may not provide us with any competitive advantages;
- we may not develop additional proprietary technologies that are patentable;
- our competitors might conduct research and development activities in countries where we do not have patent rights or where patent protection is weak and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- we cannot ensure that we will be able to successfully commercialize our product candidate on a substantial scale, if approved, before the relevant patents that we own or license expire; or
- the patents of others may have an adverse effect on our business.

Others have filed, and in the future are likely to file, patent applications covering products and technologies that are similar, identical or competitive to ours or important to our business. We cannot be certain that any patent application owned by a third party will not have priority over patent applications filed or in-licensed by us, or that we or our licensors will not be involved in interference, opposition or invalidity proceedings before U.S. or non-U.S. patent offices.

We cannot be certain that claims in an issued patent covering our product candidate will be considered patentable by the USPTO, courts in the United States, or by patent offices and courts in foreign countries. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property internationally.

The strength of patents in the biotechnology and pharmaceutical fields involves complex legal and scientific questions and can be uncertain. Patent applications that we file or in-license may fail to result in issued patents with claims that cover our product candidate in the United States or in foreign countries. Even if such patents do successfully issue, third parties may challenge the ownership, validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Any successful opposition to our patents could deprive us of exclusive rights necessary for the successful commercialization of our product candidate. Further, even if they are unchallenged, our patents may not adequately protect our intellectual property, provide exclusivity for our product candidate or prevent others from designing around our claims. If the breadth or strength of protection provided by our patents with respect to our product candidate is threatened, it could dissuade companies from collaborating with us to develop, or threaten our ability to commercialize, our product candidate.

For U.S. patent applications in which claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the USPTO to determine who was the first to invent any of the subject matter covered by the patent claims of our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our participation in an interference proceeding may fail and, even if successful, may result in substantial costs and distract our management and other employees.

For U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act, or America Invents Act, was signed into law. The America Invents Act includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. The USPTO is developing regulations and procedures to govern the administration of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and in particular, the “first to file” provisions, were enacted on March 16, 2013. This will require us to be cognizant going forward of the time from invention to filing of a patent

application and be diligent in filing patent applications, but circumstances could prevent us from promptly filing patent applications on our inventions. It remains unclear what impact the America Invents Act will have on the operation of our business.

As such, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

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

The term of any individual patent depends on applicable law in the country where the patent is granted. In the United States, provided all maintenance fees are timely paid, a patent generally has a term of 20 years from its application filing date or earliest claimed non-provisional filing date. Extensions may be available under certain circumstances, but the life of a patent and, correspondingly, the protection it affords is limited. When the terms of all patents covering our product candidate expire, our business may become subject to competition from competitive products, including biosimilar version of our products.

Our product candidate is protected by patents covering the composition of matter and methods of using sabirnetug. The patents in this portfolio are expected to expire in 2031 without taking into account any possible extensions and assuming payment of all appropriate maintenance, renewal, annuity, or other governmental fees. We cannot be certain that we will file and, if filed, obtain patent protection for our product candidate beyond our rights in the current sabirnetug patent portfolio. If we are unable to obtain additional patent protection on sabirnetug, our primary protection from biosimilar market entry will be limited to regulatory biologic exclusivity.

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

Depending upon the timing, duration and specifics of any FDA marketing approval of our product candidate, one or more patents issuing from U.S. patent applications that we file or license may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984, or 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 Supplemental Protection Certificate. If we encounter delays in our development efforts, including our future clinical trials, the period of time during which we could market our product candidate under patent protection would be reduced. Additionally, we may not receive an extension if we fail to apply within applicable deadlines, fail to apply prior to expiration of relevant patents, or otherwise fail to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following our patent expiration, and our revenue could be reduced.

If we fail to comply with our obligations in the agreements under which we license intellectual property rights from third parties, or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.

Licensing of intellectual property rights is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise between us and our licensors regarding intellectual property rights subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property rights of the licensor that are not subject to the license agreement;
- our right to sublicense intellectual property rights to third parties under collaborative development relationships;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidate, and what activities satisfy those diligence obligations; and

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms and/or to secure our rights to the licensed intellectual property, our business, results of operations, financial condition and prospects may be adversely affected. We may enter into additional licensing arrangements in the future and, if we fail to comply with obligations under those agreements, we could suffer adverse consequences.

We were a party to a collaboration agreement with Merck to research, discover and develop certain technology related to Aß-derived diffusible ligands, or ADDLs. This collaboration was initiated in 2003 and was later terminated by Merck in 2011. During the collaboration, sabirnetug, an ADDL-binding antibody, was developed and intellectual property was filed by Merck. Under the surviving provisions of the collaboration agreement, Merck exclusively licensed Merck's interest in patent rights claiming ADDL antibodies, ADDL antigens and/or products to Acumen. If a dispute were to arise in the future as to our rights to the intellectual property under the agreement, our ability to commercialize sabirnetug may be jeopardized.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patents and/or applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of the patents and/or applications. We have systems in place to remind us to pay these fees, and we employ outside counsel to pay these fees due to foreign patent agencies. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations 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, our competitors might be able to enter the market with similar or identical products or technology earlier than should otherwise have been the case, which would have a material adverse effect on our business, financial condition, results of operations and prospects.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidate.

As is the case with other biotechnology and pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Our patent rights may be affected by developments or uncertainty in U.S. or foreign patent statutes, patent case law, USPTO rules and regulations or the rules and regulations of foreign patent offices. Obtaining and enforcing patents in the biotechnology and pharmaceutical industry involve both technological and legal complexity, and are therefore costly, time-consuming and inherently uncertain. In addition, the United States may, at any time, enact changes to U.S. patent law and regulations, including by legislation, by regulatory rule-making, or by judicial precedent, that adversely affect the scope of patent protection available and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and/or damages. For example, the scope of patentable subject matter under 35 U.S.C. 101 has evolved significantly over the past several years as the Court of Appeals for the Federal Circuit and the Supreme Court issued various opinions, and the USPTO modified its guidance for practitioners on multiple occasions. Other countries may likewise enact changes to their patent laws in ways that adversely diminish the scope of patent protection and weaken the rights of patent owners to obtain patents, enforce patent infringement and obtain injunctions and/or damages.

Further, the United States and other governments may, at any time, enact changes to law and regulation that create new avenues for challenging the validity of issued patents. For example, the America Invents Act created new administrative post-grant proceedings, including post-grant review, inter partes review, and derivation proceedings that allow third parties to challenge the validity of issued patents. This applies to all of our U.S. patents, even those issued before March 16, 2013. Because of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in U.S. 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. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on

decisions by the U.S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

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

Patents are of national or regional effect. Filing, prosecuting and defending patents on our product candidate, and other proprietary technologies we develop in all countries throughout the world would be prohibitively expensive. In addition, the laws of some foreign countries do not protect intellectual property rights in the same manner and to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States. Competitors may use our 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 have patent protection, but enforcement of such patent protection is not as strong as that in the United States. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing.

The requirements for patentability may differ in certain countries. For example, unlike other countries, China has a heightened requirement for patentability, and specifically requires a detailed description of medical uses of claimed drug. In India, unlike the United States, there is no link between regulatory approval for a drug and its patent status. In addition to India, certain countries in Europe and developing countries, including China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors.

In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities.

Accordingly, our efforts to enforce intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology or pharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

We may become subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may be subject to claims that former employees (including former employees of our licensors), collaborators or other third parties have an interest in our patent rights, trade secrets, 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. For example, we may have inventorship disputes 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 candidate 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 and/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 have a material adverse effect on 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 and other employees.

We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through in-licenses.

Presently we have intellectual property rights to our product candidate sabirnetug through a license from Merck. We also have an intellectual property license through a license with Northwestern University, or Northwestern, and, if this agreement remains in place, we could be required to pay low single digit royalties to Northwestern in the future. We entered into a single product license agreement with Lonza Sales AG, or Lonza, on November 2, 2022, for non-exclusive access to Lonza's glutamine synthetase gene expression system known as the GS System®, to use, develop and manufacture sabirnetug. Additionally, we entered into a non-exclusive collaboration and license agreement with Halozyme in November 2023 with respect to the development of a subcutaneous formulation of sabirnetug, and we entered into a collaboration, option and license agreement with JCR in July 2025 to develop an Aß oligomer-targeted EBD™ therapy for AD. Because our program may require the use of additional proprietary rights held by third parties, the growth of our business will likely depend in part on our ability to acquire, in-license or use these proprietary rights. In addition, our product candidate may require specific formulations to work effectively and efficiently and these rights may be held by others. We may be unable to acquire or in-license, on reasonable terms, proprietary rights related to any compositions, formulations, methods of use, processes or other intellectual property rights from third parties that we identify as being necessary for our product candidate. Even if we are able to obtain a license to such proprietary rights, it may be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In that event, we may be required to expend significant time and resources to develop or license replacement technology.

Where we obtain licenses from or collaborate with third parties, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain or enforce the patents, covering technology that we license from third parties, or such activities, if controlled by us, may require the input of such third parties. If any of our licensors or collaboration partners fail to prosecute, maintain and enforce such patents and patent applications in a manner consistent with the best interests of our business, including by payment of all applicable fees for patents covering our product candidate, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, our ability to develop and commercialize our product candidate may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. In addition, even where we have the right to control patent prosecution of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution. We may also require the cooperation of our licensors and collaborators to enforce any licensed patent rights, and such cooperation may not be provided. Therefore, these patents and applications may not be prosecuted and enforced in a manner consistent with the best interests of our business, or in compliance with applicable laws and regulations, which may affect the validity and enforceability of such patents or any patents that may issue from such application.

Moreover, we will likely have obligations under our current or future licenses, including making royalty and milestone payments, and any failure to satisfy those obligations could give our licensor the right to terminate the license. Termination of a necessary license, or expiration of licensed patents or patent applications, could have a material adverse impact on our business. Our business would suffer if any such licenses terminate, if the licensors fail to abide by the terms of the license, if the licensors fail to enforce licensed patents against infringing third parties, if the licensed patents or other rights are found to be invalid or unenforceable, or if we are unable to enter into necessary licenses on acceptable terms. Further, if any licenses terminate, or if the underlying patents fail to provide the intended exclusivity, competitors or other third parties may gain the freedom to seek regulatory approval of, and to market, products identical or similar to ours. Moreover, our licensors may own or control intellectual property that has not been licensed to us and, as a result, we may be subject to claims, regardless of their merit, that we are infringing or otherwise violating the licensor's rights. In addition, while we cannot currently determine the amount of the royalty obligations we would be required to pay on sales of future products, if any, the amounts may be significant. The amount of our future royalty obligations will depend on the technology and intellectual property we use in products that we successfully develop and commercialize, if any. Therefore, even if we successfully develop and commercialize products, we may be unable to achieve or maintain profitability.

The licensing and acquisition of third-party proprietary rights is a competitive area, and other companies, which may be more established or have greater resources than we do, may also be pursuing strategies to license or acquire third-party proprietary rights that we may consider necessary or attractive in order to commercialize our product candidate. More established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities.

For example, we have collaborated and may in the future collaborate with U.S. and foreign academic institutions to accelerate our preclinical research or development under written agreements with these institutions. Typically, these

institutions provide us with an option to negotiate an exclusive license to any of the institution's proprietary rights in technology resulting from the collaboration. Regardless of such option to negotiate a license, we may be unable to negotiate a license within the specified time frame or under terms that are acceptable to us. If we are unable to do so, the institution may offer, on an exclusive basis, its proprietary rights to other parties, potentially blocking our ability to pursue our program. In addition, disputes may arise under our existing or future license agreements with these institutions or with other counterparties which may, among other things, lead to the termination or renegotiation of these agreements, or otherwise require us to incur significant financial obligations.

In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us, either on reasonable terms, or at all. 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 on commercially reasonable terms, our ability to commercialize our products, and our business, financial condition, and prospects for growth, could suffer.

Third-party claims alleging intellectual property infringement may prevent or delay our drug discovery and development efforts.

Our success depends in part on our avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including inter partes review, interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. The America Invents Act introduced new procedures including inter partes review and post-grant review. The implementation of these procedures brings uncertainty to the possibility of challenges to our patents in the future and the outcome of such challenges. Numerous U.S. 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 candidate. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our activities related to our product candidate may give rise to claims of infringement of the patent rights of others.

The pharmaceutical and biotechnology industries have produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. We cannot assure you that any of our current or future product candidates will not infringe existing or future patents. We may not be aware of patents that have already issued that a third party might assert are infringed by one of our current or future product candidates.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third-party patents of which we are currently unaware with claims to materials, compositions, formulations, methods of manufacture or methods for treatment related to our product candidate, or the use or manufacture of our product candidate. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be currently pending third-party patent applications which may later result in issued patents that our product candidate, and other proprietary technologies may infringe, or which such third parties claim are infringed by the use of our technologies. Parties making claims against us for infringement or misappropriation of their intellectual property rights may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize our product candidate. Defense of these claims, regardless of their merit, could involve substantial expenses and could be a substantial diversion of management and other employee resources from our business.

If we collaborate with third parties in the development of technology in the future, our collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our intellectual property or proprietary information or expose us to litigation or potential liability. Further, collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability. In the future, we may agree to indemnify our commercial collaborators against certain intellectual property infringement claims brought by third parties.

Responding to any claims of patent infringement asserted by third parties would be time-consuming and could:

- result in costly litigation;
- divert the time and attention of our technical personnel and management;
- cause development delays;

- prevent us from commercializing our product candidate until the asserted patent expires or is finally held invalid, unenforceable, or not infringed in a court of law;
- require us to develop non-infringing technology, which may not be possible on a cost-effective basis;
- require us to pay damages to the party whose intellectual property rights we may be found to be infringing, which may include treble damages if we are found to have been willfully infringing such intellectual property;
- require us to pay the attorney's fees and costs of litigation to the party whose intellectual property rights we may be found to be willfully infringing; and/or
- require us to enter into royalty or license agreements, which may not be available on commercially reasonable terms, or at all.

If we are sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do either. Proving invalidity or unenforceability is difficult. For example, in the United States, proving invalidity before federal courts requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and divert management's time and attention in pursuing these proceedings, which could have a material adverse effect on us. If we are unable to avoid infringing the patent rights of others, we may be required to seek a license, which may not be available, defend an infringement action or challenge the validity or enforceability of the patents in court. Patent litigation is costly and time-consuming. We may not have sufficient resources to bring these actions to a successful conclusion. In addition, if we do not obtain a license, develop or obtain non-infringing technology, fail to defend an infringement action successfully or have infringed patents declared invalid or unenforceable, we may incur substantial monetary damages, encounter significant delays in bringing our product candidate to market and be precluded from developing, manufacturing or selling our product candidate.

We do not always conduct independent reviews of pending patent applications and patents issued to third parties. We cannot be certain that any of our or our licensors' patent searches or analyses, including but not limited to the identification of relevant patents, analysis of the scope of relevant patent claims or determination of 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, Europe and elsewhere that is relevant to or necessary for the commercialization of our product candidate in any jurisdiction, because:

- some patent applications in the United States may be maintained in secrecy until the patents are issued;
- 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;
- pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our product candidate or their uses;
- identification of third-party patent rights that may be relevant to our technology 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;
- patent applications in the United States are typically not published until 18 months after the priority date; and
- publications in the scientific literature often lag behind actual discoveries.

Further, 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 and can involve other factors such as expert opinion. Our interpretation of the relevance or the scope of claims in a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. Further, we may incorrectly determine that our technologies or product candidate are not covered by a third-party patent or may incorrectly predict whether a third party's pending patent application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or internationally that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products or product candidate.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours, and others may have or obtain patents or proprietary rights that could limit our ability to make, use, sell, offer for sale or import our product candidate or future products or impair our competitive position. Numerous third-party U.S. and foreign issued

patents and pending patent applications exist in the fields in which we are developing our product candidate. There may be third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidate. Any such patent application may have priority over one of our patent applications, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a U.S. patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions. Other countries have similar laws that permit secrecy of patent applications and may be entitled to priority over our applications in such jurisdictions.

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.

If a third party prevails in a patent infringement lawsuit against us, we may have to stop making and selling the infringing product, pay substantial damages, including treble damages and attorneys' fees if we are found to be willfully infringing a third party's patents, 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. Further, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidate. 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 candidate, which could harm our business significantly. Even if we were able to obtain a license, the rights may be non-exclusive, which may give our competitors access to the same intellectual property.

We may be subject to claims that we have wrongfully hired an employee from a competitor or that we or our employees have wrongfully used or disclosed alleged confidential information or trade secrets of their former employers.

As is common in the biotechnology and pharmaceutical industries, in addition to our employees, we engage the services of consultants to assist us in the development of our product candidate, and other proprietary technologies. Many of these consultants, and many of our employees, were previously employed at, or may have previously provided or may be currently providing consulting services to, other pharmaceutical companies including our competitors or potential competitors. We may become subject to claims that we, our employees or a consultant inadvertently or otherwise used or disclosed trade secrets or other information proprietary to their former employers or their former or current clients. 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 or personnel, which could adversely affect our business. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to our management team and other employees.

We may be involved in lawsuits to protect or enforce our patents or the patents of our licensors, which could be expensive, time-consuming, and unsuccessful. Further, our issued patents could be found invalid or unenforceable if challenged in court, and we may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Third parties including competitors may infringe, misappropriate or otherwise violate our patents, patents that may issue to us in the future, or the patents of our licensors that are licensed to us. To counter infringement or unauthorized use, we may need to or choose to file infringement claims, which can be expensive and time-consuming. We may not be able to prevent, alone or with our licensors, infringement, misappropriation or other violation of our intellectual property, particularly in countries where the laws may not protect those rights as fully as in the United States, or if we require, but do not receive, the consent or cooperation of our licensors to enforce such intellectual property.

If we choose to go to court to stop another party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid, unenforceable, or should not be enforced against that third party for any number of reasons. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge include an alleged failure to meet any of several statutory requirements for patentability, including lack of novelty, obviousness, lack of written description, indefiniteness or non-enablement. Grounds for an unenforceability assertion could include an allegation that someone

connected with prosecution of the patent withheld relevant information from the USPTO or made a misleading statement during prosecution, i.e., committed inequitable conduct. Third parties may also raise similar claims before the USPTO, even outside the context of litigation. Similar mechanisms for challenging the validity and enforceability of a patent exist in foreign patent offices and courts and may result in the revocation, cancellation or amendment of any foreign patents we or our licensors hold now or in the future. The outcome following legal assertions of invalidity and unenforceability is unpredictable, and prior art could render our patents or those of our licensors invalid. If a defendant were to prevail on a legal assertion of invalidity and/or unenforceability, we would lose at least part, and perhaps all, of the patent protection on such product candidate. Such a loss of patent protection would have a material adverse impact on our business.

Interference or derivation proceedings provoked by third parties or brought by us or declared by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms or at all, or if a non-exclusive license is offered and our competitors gain access to the same technology. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to conduct our future clinical trials, continue our research programs, license necessary technology from third parties, or enter into development or manufacturing partnerships that would help us bring our product candidate to market.

We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could compromise our ability to compete in the marketplace. Even if resolved in our favor, litigation or other legal proceedings relating to our intellectual property rights may cause us to incur significant expenses and could distract our technical and management personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions, or other interim proceedings or developments and if securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation.

Our ability to enforce our patent rights depends on our ability to establish standing in a court of competent jurisdiction. Whether a patent holder or licensee of a patent has standing can be uncertain and the considerations complex. However, if a licensor is required to be joined, and they are unwilling to do so, we may be unable to proceed with an infringement action.

Our ability to enforce our patent rights depends on our ability to detect infringement. It may be difficult to detect infringers who do not advertise the components or methods that are used in connection with their products and services. Moreover, it may be difficult or impossible to obtain evidence of infringement in a competitor's or potential competitor's product or service. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded if we were to prevail may not be commercially meaningful.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that even if a third party is infringing our issued patent or patents that may issue from patent applications or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

We rely on trade secrets to protect our proprietary technologies, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and/or other advisors, and inventions

agreements with employees, consultants and advisors, to protect our trade secrets and other proprietary information. In addition to contractual measures, we try to protect the confidential nature of our proprietary information using commonly accepted physical and technological security measures. Despite these efforts, we cannot provide any assurances that all such agreements have been duly executed, and these agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. For example, the FDA, as part of its Transparency Initiative, is currently considering whether to make additional information publicly available on a routine basis, including information that we may consider to be trade secrets or other proprietary information, and it is not clear at the present time how the FDA's disclosure policies may change in the future, if at all. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and failure to obtain or maintain trade secret protection could adversely affect our competitive business position.

In addition, such security measures may not provide adequate protection for our proprietary information, for example, in the case of misappropriation of a trade secret by an employee, consultant, customer or third party with authorized access. Our security measures may not prevent an employee, consultant or customer from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. Unauthorized parties may also attempt to copy or reverse engineer certain aspects of our products that we consider proprietary. Even though we use commonly accepted security measures, the criteria for protection of trade secrets can vary among different jurisdictions.

Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time-consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. Moreover, third parties may still obtain this information or may come upon this or similar information independently, and we would have no right to prevent them from using that technology or information to compete with us. Trade secrets will over time be disseminated within the industry through independent development, the publication of journal articles, and the movement of personnel skilled in the art from company to company or academic to industry scientific positions. Though our agreements with third parties typically restrict the ability of our advisors, employees, collaborators, licensors, suppliers, third-party contractors and/or consultants to publish data potentially relating to our trade secrets, our agreements may contain certain limited publication rights. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor, we would have no right to prevent such competitor from using that technology or information to compete with us, which could harm our competitive position. Because from time to time we expect to rely on third parties in the development, manufacture and distribution of our products and provision of our services, we must, at times, share trade secrets with them. Despite employing the contractual and other security precautions described above, the need to share trade secrets increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others or are disclosed or used in violation of these agreements. If any of these events occurs or if we otherwise lose protection for our trade secrets, the value of this information may be greatly reduced and our competitive position would be harmed. If we do not apply for patent protection prior to such publication or if we cannot otherwise maintain the confidentiality of our proprietary technology and other confidential information, then our ability to obtain patent protection or to protect our trade secret information may be jeopardized.

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 trademarks or trade names, once registered, may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. 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 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 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. We may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our financial condition or results of operations.

Moreover, any names we may propose 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. 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, it 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. Similar requirements exist in Europe. Further, 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. 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. 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.

Intellectual property discovered through government funded programs may be subject to federal regulations such as "march-in" rights, certain reporting requirements and a preference for U.S.-based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non-U.S. manufacturers.

Some of our patents may have been generated through the use of U.S. government funding, and we may acquire or license in the future intellectual property rights that have been generated through the use of U.S. government funding or grants. Pursuant to the Bayh-Dole Act of 1980, the U.S. government has certain rights in inventions developed with government funding. These U.S. government rights include a non-exclusive, non-transferable, irrevocable worldwide license to use inventions for any governmental purpose. In addition, the U.S. government has the right, under certain limited circumstances, to require us to grant exclusive, partially exclusive, or non-exclusive licenses to any of these inventions to a third party if it determines that: (1) adequate steps have not been taken to commercialize the invention; (2) government action is necessary to meet public health or safety needs; or (3) government action is necessary to meet requirements for public use under federal regulations (also referred to as "march-in rights"). If the U.S. government exercised its march-in rights in our existing or future intellectual property rights that are generated through the use of U.S. government funding or grants, we could be forced to license or sublicense intellectual property developed by us or that we license on terms unfavorable to us, and there can be no assurance that we would receive compensation from the U.S. government for the exercise of such rights. The U.S. government also has the right to take title to these inventions if the grant recipient fails to disclose the invention to the government or fails to file an application to register the intellectual property within specified time limits. Intellectual property generated under a government funded program is also subject to certain reporting requirements, compliance with which may require us to expend substantial resources. In addition, the U.S. government requires that any products embodying any of these inventions or produced through the use of any of these inventions be manufactured substantially in the United States. This preference for U.S. industry may be waived by the federal agency that provided the funding if the owner or assignee of the intellectual property can show that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible. This preference for U.S. industry may limit our ability to contract with non-U.S. product manufacturers for products covered by such intellectual property.

Risks Related to Legal and Regulatory Compliance Matters

Our business operations, including our relationships with healthcare providers, such as physicians, third-party payors, patients, other customers or organizations in a position to influence current and future business, are subject, directly or indirectly, to extensive regulation under healthcare laws. If we are unable to comply, or have not fully complied, with such laws, we could face substantial penalties.

Our business operations and current and future arrangements with healthcare providers, including physicians, third-party payors, patients, other customers or other parties in a position to influence current and future business subject us to various federal and state fraud and abuse laws and other healthcare laws. These laws will impact, among other things, our current research activities and any future educational, promotional, and other activities related to the commercialization of any products we may market and the operation of our business generally. The laws that affect our operations, some of which may apply only if and when we have a marketed product include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, individuals or entities from knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe or rebate),

directly or indirectly, overtly or covertly, in cash or in kind in return for, or to induce, either the referral of an individual, or the purchase, lease, order or arrangement for or recommendation of the purchase, lease, order or arrangement for any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" has been broadly interpreted to include anything of value. A person does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly;

- the federal civil and criminal false claims laws, including, without limitation, the federal False Claims Act, or FCA, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false or fraudulent or knowingly making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer of remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable to Medicare or a state health program, unless an exception applies;
- HIPAA, which created additional federal criminal statutes which prohibit, among other things, a person from knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors and knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for 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 the Health Information Technology for Economic and Clinical Health Act, and their implementing regulations, also imposes obligations on "covered entities," including certain healthcare providers, health plans, healthcare clearinghouses, and their respective "business associates," if those business associates create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity as well as the business associates' covered subcontractors, with respect to safeguarding the privacy, security and transmission of individually identifiable health information, as well as analogous state and foreign laws that govern the privacy and security of health information in some circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts;
- the FDCA, which, among other things, strictly regulates drug product and medical device marketing, prohibits manufacturers from marketing such products for off-label use and regulates the distribution of samples;
- federal laws, such as the Medicaid Drug Rebate Program, 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 governmental healthcare programs;
- the so-called federal "sunshine law" or Open Payments which requires manufacturers of drugs, devices, biologics, and medical supplies to report to the Centers for Medicare & Medicaid Services information related to payments and other transfers of value to teaching hospitals, physicians, and other healthcare practitioners, as well as ownership and investment interests held by physicians and their immediate family members;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- analogous state laws and regulations, such as state anti-kickback and false claims laws, which 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 state laws which regulate interactions between pharmaceutical companies and healthcare providers, require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, require pharmaceutical companies to report information on transfers of value to other healthcare

providers, marketing expenditures or pricing information and/or require licensing or registration of sales representatives.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

Given the breadth of the laws and regulations and narrowness of any exceptions, limited guidance for certain laws and regulations and evolving government interpretations of the laws and regulations, governmental authorities may possibly conclude that our business practices are non-compliant. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to penalties, including, without limitation, civil and criminal penalties, damages, fines, imprisonment, exclusion from participating in federal and state funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, contractual damages, diminished profits and future earnings, reputational harm and the curtailment or restructuring of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business.

Even if we obtain regulatory approval for sabirnetug or any future product candidates, they will remain subject to ongoing regulatory oversight, which may result in significant additional expense.

Even if we obtain regulatory approval for sabirnetug or any future product candidates, such product candidates will be subject to ongoing regulatory requirements applicable to research, development, testing, manufacturing, labeling, packaging, storage, advertising, promoting, sampling, record-keeping and submission of safety and other post-market information, among other things. Any regulatory approvals that we receive for sabirnetug or any future product candidates may also be subject to REMS, limitations on the approved indicated uses for which the drug may be marketed or to the conditions of approval or requirements that we conduct potentially costly post-marketing testing and surveillance studies, including Phase 4 trials and surveillance to monitor the quality, safety and efficacy of the drug. An unsuccessful post-marketing study or failure to complete such a study could result in the withdrawal of marketing approval. We will further be required to immediately report any serious and unexpected adverse events and certain quality or production problems with our products to regulatory authorities along with other periodic reports. Any new legislation addressing drug safety issues could result in delays in product development or commercialization, or increased costs to assure compliance. We cannot predict the likelihood, nature or extent of government regulation that may arise from future 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 lose any marketing approval that we may have obtained and we may not achieve or sustain profitability.

In addition, drug manufacturers are subject to payment of user fees and continual review and periodic inspections by the FDA and other comparable regulatory authorities for compliance with cGMP requirements and adherence to commitments made in the BLA or foreign marketing application. If we, or a regulatory authority, discover previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured or if a regulatory authority disagrees with the promotion, marketing or labeling of that drug, a regulatory authority may impose restrictions relative to that drug, the manufacturing facility or us, including requesting a recall or requiring withdrawal of the drug from the market or suspension of manufacturing.

If we fail to comply with applicable regulatory requirements following approval of sabirnetug or any future product candidates, a regulatory authority may:

- issue an untitled letter or warning letter asserting that we are in violation of the law;
- seek an injunction or impose administrative, civil or criminal penalties or monetary fines;
- issue a safety alert, Dear Healthcare Provider letter, press release or other communication containing warnings or safety information about the product;
- mandate corrections to promotional materials and labeling or issuance of corrective information;

- suspend or withdraw regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve a pending marketing application or supplement to an approved application or comparable foreign marketing application (or any supplements thereto) submitted by us or our strategic partners;
- restrict the marketing or manufacturing of the drug;
- seize or detain the drug or otherwise require the withdrawal of the drug from the market;
- refuse to permit the import or export of products or product candidates; or
- refuse to allow us to enter into supply contracts, including government contracts.

Any government investigation of alleged violations of law could require us to expend significant time and resources in response and could generate negative publicity. The occurrence of any event or penalty described above may inhibit our ability to commercialize sabirnetug or any future product candidates and harm our business, financial condition, results of operations and prospects.

Even if we obtain FDA or EMA approval for any of our product candidates in the United States or European Union, we may never obtain approval for or commercialize any of them in any other jurisdiction, which would limit our ability to realize their full market potential.

In order to market any products in any particular jurisdiction, we must establish and comply with numerous and varying regulatory requirements on a country-by-country basis regarding safety and efficacy.

Approval by the FDA in the United States or the EMA in the European Union does not ensure approval by regulatory authorities in other countries or jurisdictions. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval elsewhere. In addition, clinical trials conducted in one country may not be accepted by regulatory authorities in other countries, and regulatory approval in one country does not guarantee regulatory approval in any other country.

Approval processes vary among countries and can involve additional product testing and validation and additional administrative review periods. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our products is also subject to approval.

Seeking foreign regulatory approval could result in difficulties and increased costs for us and require additional nonclinical studies or clinical trials which could be costly and time-consuming. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our products in those countries. We do not have any product candidates approved for sale in any jurisdiction, including in international markets, and we do not have experience in obtaining regulatory approval in international markets. If we fail to comply with regulatory requirements in international markets or to obtain and maintain required approvals, or if regulatory approvals in international markets are delayed, our target market will be reduced and our ability to realize the full market potential of any product we develop will be unrealized.

Healthcare legislative or regulatory reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post-approval activities, and affect our ability to profitably sell any product candidates for which we obtain marketing approval.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and expanding access. In the United States, the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. For example, in 2010, the ACA was enacted, which, among other things, subjected biologic products to potential competition by lower-cost biosimilars; addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug

Rebate Program; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations; subjected manufacturers to new annual fees and taxes for certain branded prescription drugs; and created a new Medicare Part D coverage gap discount program. More generally, the ACA expanded healthcare coverage through Medicaid expansion and the implementation of the "individual mandate" for health insurance coverage.

Beyond the ACA, there have been ongoing healthcare reform efforts, including efforts focused on drug pricing and payment. For example, the Inflation Reduction Act of 2022, or IRA, includes a number of changes intended to address rising prescription drug prices in Medicare Parts B and D. These changes include caps on Medicare Part D out-of-pocket costs, Medicare Part B and Part D drug price inflation rebates, a new Medicare Part D manufacturer discount drug program (replacing the previous ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs (with negotiated prices for the first set of drugs scheduled to take effect in 2026). The IRA has had and will likely continue to have a significant impact on the pharmaceutical industry. Additionally, changes to Medicaid effective in 2024 eliminated the Medicaid rebate cap, and changes to certain Medicare price reporting requirements for drugs beginning in 2026 will likely increase the administrative and compliance burden for manufacturers.

More recently, President Trump issued an Executive Order in April 2025 with multiple directives aimed at lowering drug prices, including refining the Medicare drug price negotiation program established by the IRA; accelerating competition for high-cost prescription drugs by accelerating approval of generics and biosimilars and facilitating the process for re-classifying prescription drugs as over-the-counter drugs; and increasing drug importation. In May 2025, President Trump issued another Executive Order that directed government agencies and officials to identify most-favored nation pricing targets for prescription drugs (and looked to pharmaceutical manufacturers to make significant progress towards delivering target prices to patients); prevent foreign countries from disproportionately shifting the cost of global pharmaceutical research and development to the United States; and facilitate direct-to-consumer purchasing programs for pharmaceutical manufacturers to sell their products to patients at the most-favored-nation price. In the wake of the Executive Orders and related executive initiatives, a number of pharmaceutical manufacturers have announced direct-to-consumer offerings with discounted prices and/or reached agreement with the federal government regarding pricing for drugs, including prices for Medicaid drugs and newly launched products. A website sponsored by the federal government offering pharmaceutical direct-to-consumer channels has also been launched. Federal agencies are developing new drug pricing pilot programs, such as a voluntary Medicaid initiative which would authorize the federal government to negotiate Medicaid supplemental rebates with participating manufacturers on behalf of state Medicaid programs, in exchange for standardized coverage criteria for participating manufacturer drugs, and proposed Medicare Part B and Part D pilot models that, if finalized as proposed, would replace existing inflation-based Medicare rebates with rebates determined on the basis of international prices, for drugs and patients subject to the model. Many of these reform initiatives would require additional legal and/or administrative action to implement and may be subject to legal challenge.

Other federal healthcare reform efforts or actions may affect access to healthcare coverage or the funding of healthcare benefits, although the full impact of such efforts or actions cannot be predicted. For example, the Congressional Budget Office has estimated that Medicaid provisions in the 2025 budget reconciliation legislation, including restrictions in eligibility and funding for Medicaid, as well as changes to the healthcare marketplace, such as the elimination of certain subsidies, will increase the number of uninsured.

Individual states in the United States have also become increasingly active in implementing 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. Healthcare reform efforts have been and may continue to be subject to scrutiny, legal challenge and subsequent amendment, creating further uncertainty.

Other recent government actions may also affect prices or payments for prescription drugs. For example, the current presidential administration's recently announced tariff on branded or patented drugs may increase the cost of drug products that are imported from abroad or manufactured using products or materials imported from abroad. The timeline for implementation of this tariff has not yet been finalized. As another example, the Budget Control Act of 2011, as amended, resulted in the imposition of reductions in Medicare (but not Medicaid) payments to providers in 2013 and will remain in effect into 2032 unless additional Congressional action is taken. Any significant spending reductions affecting Medicare, Medicaid or other publicly funded or subsidized health programs that may be implemented and/or any significant taxes or fees that may be imposed on us could have an adverse impact on our results of operations.

We expect that these and other reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug. 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 drugs. We cannot, however, predict the ultimate content, timing or effect of any federal and state reform efforts. There is no assurance that federal or state healthcare reform will not adversely affect our future business and financial results.

In addition, FDA regulations and guidance may be revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new regulations or guidance, or revisions or reinterpretations of existing regulations or guidance, may impose additional costs or lengthen FDA review times for sabirnetug or any other product candidate we may develop. We cannot determine how changes in regulations, statutes, policies or interpretations, when and if issued, enacted or adopted, may affect our business in the future. Such changes could, among other things, require:

- additional clinical trials to be conducted prior to obtaining approval;
- changes to manufacturing methods;
- recalls, replacements or discontinuance of one or more of our products; and
- additional recordkeeping.

Such changes would likely require substantial time and impose significant costs or could reduce the potential commercial value of sabirnetug or other product candidates, which could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory authorizations or approvals for any other products would harm our business, financial condition and results of operations.

The U.S. Supreme Court's June 2024 decision in *Loper Bright Enterprises v. Raimondo* overturned the longstanding *Chevron* doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The *Loper* decision could result in additional legal challenges to regulations and guidance issued by federal agencies, including the FDA, on which we rely. Any such legal challenges, if successful, could have a material impact on our business. Additionally, the *Loper* decision may result in increased regulatory uncertainty, inconsistent judicial interpretations, and other impacts to the agency rulemaking process, any of which could adversely impact our business and operations. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action or as a result of legal challenges, 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, our business could be materially harmed.

Our business activities may be subject to the U.S. Foreign Corrupt Practices Act of 1977, or FCPA, and similar anti-bribery and anti-corruption laws.

Our business activities may be subject to the FCPA, U.S. domestic bribery statutes, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we may operate, including the UK Bribery Act of 2010. The FCPA generally prohibits offering, promising, giving or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Additionally, in many other countries, hospitals are owned and operated by the government, and doctors and other hospital employees would be considered foreign officials under the FCPA. There is no certainty that all of our employees, agents, contractors or those of our affiliates will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers or our employees, the closing down of our facilities, implementation of compliance programs and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our product candidates in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees and our business, prospects, operating results and financial condition.

Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading, which could significantly harm our business.

We are exposed to the risk of fraud or other misconduct by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-U.S. regulators, provide accurate information to the FDA and non-U.S. regulators, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, 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. 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. 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 these laws or regulations. If any such actions are instituted against us, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity or a natural disaster.

In the ordinary course of our business, we and our third-party service providers, such as CROs, collect, maintain and transmit sensitive data on our networks and systems, including our intellectual property and proprietary or confidential business information (such as research data and personal information). The secure maintenance of this information is critical to our business and reputation. In addition, we are heavily dependent on the functioning of our information technology infrastructure to carry out our business processes. While we have adopted administrative, technical and physical safeguards to protect such systems and data, our systems and those of our third-party service providers may still be vulnerable to cyberattacks.

There are growing risks related to the security, confidentiality and integrity of personal and corporate information stored and transmitted electronically due to increasingly diverse and sophisticated threats to networks, systems and data security. Potential attacks span a spectrum from attacks by criminal hackers, hacktivists and nation state or state-sponsored actors, to employee malfeasance and human or technological error. Cyberattacks against companies like ours have increased in frequency and potential harm over time, and the methods used to gain unauthorized access constantly evolve, making it increasingly difficult to anticipate, prevent and/or detect incidents successfully in every instance. In addition, many of our employees work remotely, which may increase our vulnerability to cyber and other information technology risks. We are required to expend significant resources in an effort to protect against security incidents and may be required or choose to spend additional resources or modify our business activities, particularly where required by applicable data privacy and security laws or regulations or industry standards.

Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely (including our vendors, contractors and other third-party partners who process information on our behalf or have access to our systems), are vulnerable to damage from computer viruses, malware, ransomware, phishing attacks and other forms of social engineering, denial-of-service attacks, business email compromise, third-party or employee theft or misuse and other negligent actions, natural disasters, terrorism, war, telecommunication and electrical failures, cyberattacks or cyber-intrusions, security incidents, disruptions, and persons inside our organization or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through cyberattacks or cyber intrusion, including by computer hackers, foreign governments and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. For example, the loss of clinical trial data from completed, ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of or damage to our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur material legal claims (including class claims) and liability, substantial remediation costs, regulatory enforcement, liability under data protection laws, additional reporting requirements and damage to our reputation, and the further development of our product candidates could be delayed. Further, we cannot be sure that insurance will continue to be available to us on commercially reasonable terms (if at all), or that any insurer will not deny coverage as to any future claim.

As cybersecurity threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business.

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 general liability, products liability and directors' and officers' insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of sabirnetug or any other product candidate. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our financial position and results of operations.

Risks Related to Employee Matters and Managing our Growth

We will need to expand our operations and increase the size of our company, and we may experience difficulties in managing growth.

As we advance sabirnetug through clinical development, and potentially expand the number of our drug development programs, we will need to increase our drug development, scientific and administrative headcount to manage these programs. In addition, to meet our obligations as a public company, we will need to increase our general and administrative capabilities. Our management, personnel and systems currently in place may not be adequate to support this future growth. Our need to effectively manage our operations, growth and various projects requires that we:

- successfully attract and recruit new employees or consultants with the expertise and experience we will require;
- manage our clinical programs effectively, including at numerous clinical sites;
- develop a marketing and sales infrastructure; and
- continue to improve our operational, financial and management controls, reporting systems and procedures.

If we are unable to successfully manage this growth and increased complexity of operations, our business may be adversely affected.

We may not be able to manage our business effectively if we are unable to attract and retain key personnel and consultants.

We may not be able to attract or retain qualified management, finance, scientific and clinical personnel and consultants due to the intense competition for qualified personnel and consultants among biotechnology, pharmaceutical and other businesses. If we are not able to attract and retain necessary personnel and consultants 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 industry has experienced a high rate of turnover of management personnel in recent years. We are highly dependent on the research and development, clinical, regulatory and business development expertise of Daniel O'Connell, our Chief Executive Officer, James Doherty, our President and Chief Development Officer, Matthew Zuga, our Chief Financial Officer and Chief Business Officer, Eric Siemers, M.D., our Chief Medical Officer, Russell Barton, our Chief Operating Officer and Amy Schacterle, our Chief Regulatory Officer and Head of Quality. If we lose the services of any of these individuals, our ability to implement our business strategy successfully could be seriously harmed. Any of our executive officers or key employees or consultants may terminate their employment at any time. Replacing executive officers, key employees and consultants may be difficult and may take an extended period because of the limited number of individuals in our industry with the breadth of skills and experience required to develop, gain regulatory approval of and commercialize product candidates successfully. Competition to hire and retain employees and consultants from this limited pool is intense, and the risks to attracting and retaining key personnel may be exacerbated by inflationary pressures on employee wages and benefits. As a result, we may be unable to effectively hire, train, retain or motivate these additional key personnel and consultants. Our failure to retain key personnel or consultants could materially harm our business.

We have scientific and clinical advisors and consultants who assist us in formulating our research, development and clinical strategies. These advisors are not our employees and may have commitments to, or consulting or advisory contracts

with, other entities that may limit their availability to us. Non-compete agreements are not permissible or are limited by law in certain jurisdictions and, even where they are permitted, these individuals typically will not enter into non-compete agreements with us. If a conflict of interest arises between their work for us and their work for another entity, we may lose their services. In addition, our advisors may have arrangements with other companies to assist those companies in developing product candidates or technologies that may compete with ours.

If we fail to build our finance infrastructure and improve our accounting systems and controls, we may be unable to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the reporting requirements of the Securities Exchange Act of 1934, or the Exchange Act, the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the rules and regulations of Nasdaq Global Select Market, or Nasdaq, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. Further, as an emerging growth company, our independent registered public accounting firm is not required to formally attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404 until the date we are no longer an emerging growth company and are an accelerated filer. At such time, our independent registered public accounting firm may issue a report that is adverse in the event that it is not satisfied with the level at which the controls of we have documented, designed or under which we operate.

The process of building our accounting and financial functions and systems has required and will continue to require significant additional professional fees, internal costs and management efforts. For example, we currently do not have an internal audit group, and we may need to hire additional accounting and financial staff to maintain effective internal control over financial reporting. We currently rely on consultants or external service providers to assist with our financial reporting and certain technical aspects thereof, and to provide services related to our finance function to supplement our internal staff, including with respect to our account reconciliations, and the evaluation and documentation of our system of internal controls functions. Any disruptions or difficulties in maintaining or expanding our internal financial staff or the services provided by outside consultants or financial service providers, or in implementing or using our accounting and financial functions and infrastructure, could adversely affect our system of internal controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

We cannot be certain that the measures we have taken to date, and actions we may take in the future, will prevent or avoid potential future material weaknesses. If we are unable to successfully remediate any future material weaknesses in our internal control over financial reporting, if we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements and we may be unable to maintain compliance with securities law requirements regarding timely filing of periodic reports. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and our stock price could decline as a result, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities.

Risks Related to Ownership of our Common Stock and our Status as a Public Company

An active trading market for our common stock may not continue to be developed or sustained.

Prior to our initial public offering, there was no public market for our common stock. Although our common stock is listed on Nasdaq, an active trading market for our shares may never develop or be sustained. If an active market for our common stock does not develop or is not sustained, it may be difficult for you to sell shares of our common stock at an attractive price or at all. A less active or inactive market may also impair our ability to raise capital to continue to fund our operations

by selling our common stock and may impair our ability to acquire other companies or technologies by using our common stock as consideration.

The trading price of the shares of our common stock may be volatile, and purchasers of our common stock could incur substantial losses.

Our stock price may be volatile. From July 1, 2021, the date our stock began trading on Nasdaq, through March 20, 2026, our stock price fluctuated from a low of $0.86 to a high of $26.98. The stock market in general and the market for biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their common stock at or above the price paid for the shares. The market price for our common stock may be influenced by many factors, including:

- the commencement, enrollment or results of our clinical trials, including ALTITUDE-AD and any future clinical trials we may conduct, or changes in the development status of our product candidates;
- any delay in our regulatory filings for sabirnetug or any other product candidate we may develop, and any adverse development or perceived adverse development with respect to the applicable regulatory authority's review of such filings, including without limitation the FDA's issuance of a "refusal to file" letter or a request for additional information;
- delays in, or termination of, clinical trials;
- adverse regulatory decisions, including failure to receive regulatory approval of our product candidates;
- unanticipated serious safety concerns related to the use of sabirnetug or any other product candidate we develop;
- changes in financial estimates by us or by any equity research analysts who might cover our stock;
- conditions or trends in our industry;
- changes in the market valuations of similar companies;
- announcements by our competitors of new product candidates or technologies, or the results of clinical trials or regulatory decisions;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the biopharmaceutical industry;
- publication of research reports about us or our industry or positive or negative recommendations or withdrawal of research coverage by securities analysts;
- announcements by us or our competitors of significant acquisitions, strategic partnerships or divestitures;
- our relationships with our collaborators;
- announcements of investigations or regulatory scrutiny of our operations or lawsuits filed against us;
- investors' general perception of our company and our business;
- recruitment or departure of key personnel;
- overall performance of the equity markets;
- trading volume of our common stock;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;
- significant lawsuits, including patent or stockholder litigation;
- changes in the structure of healthcare payment systems;
- general political and economic conditions; and
- other events or factors, many of which are beyond our control.

The stock market in general, and Nasdaq and biotechnology companies listed on Nasdaq in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of

these companies, which have resulted in decreased stock prices for many companies notwithstanding the lack of a fundamental change in their underlying business models or prospects. Broad market and industry factors, including potentially worsening economic conditions and other adverse effects or developments may negatively affect the market price of our common stock, regardless of our actual operating performance. The realization of any of the above risks or any of a broad range of other risks, including those described in this section, could have a significant and material adverse impact on the market price of our common stock.

In addition, in the past, stockholders have initiated class action lawsuits against pharmaceutical and biotechnology companies following periods of volatility in the market prices of these companies' stock. Such litigation, if instituted against us, could cause us to incur substantial costs and divert management's attention and resources from our business.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that equity research analysts publish about us and our business. We have only limited research coverage by equity research analysts. Equity research analysts may elect not to provide research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. In the event we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our stock could decline if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which in turn could cause our stock price or trading volume to decline.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of shares of our common stock in the public market, particularly sales by our directors, executive officers and principal stockholders, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. We are unable to predict the timing or effect of such sales on the market price of our common stock.

In March 2026, we entered into a securities purchase agreement with certain institutional and accredited investors, including certain holders of more than 5% of our total common stock outstanding on the date of the securities purchase agreement, pursuant to which we issued and sold 10,833,331 shares of common stock. Pursuant to the securities purchase agreement, we are obligated to register for resale the 10,833,331 shares of common stock sold in the private placement. If these additional shares of common stock are resold, or if it is perceived that they will be resold in the public market, the trading price of our common stock could decline.

We have filed registration statements on Form S-8 under the Securities Act of 1933, as amended, or the Securities Act, registering 19,461,572 shares of common stock subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans and plan to file additional registration statements on Form S-8 for additional shares of common stock issuable under our equity incentive plans. Shares registered under these registration statements on Form S-8 can be freely sold in the public market upon issuance, subject to the vesting of the equity awards, other restrictions provided under the terms of the applicable plan or equity award and the restrictions of Rule 144 in the case of our affiliates.

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

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

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

- only one of our three classes of directors will be elected each year;

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

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

Concentration of ownership of our common stock among our existing executive officers, directors and principal stockholders may prevent new investors from influencing significant corporate decisions.

Our directors, executive officers and beneficial owners of greater than 5% of our outstanding stock and their respective affiliates beneficially own, in the aggregate, a majority of our outstanding common stock. As a result, these persons, acting together, would be able to significantly influence all matters requiring stockholder approval, including the election and removal of directors, any merger, consolidation, sale of all or substantially all of our assets or other significant corporate transactions.

Some of these persons or entities may have interests different than yours. For example, because many of these stockholders purchased their shares at prices substantially below the public offering price and have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other stockholders.

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

We are an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012, or JOBS Act, and we intend to take advantage of some of the exemptions from reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting;
- not being required to comply 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;
- reduced disclosure obligations regarding executive compensation in our periodic reports, proxy statements and registration statements; and
- not being required to hold a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We may take advantage of these reporting exemptions until we are no longer an emerging growth company. We will remain an emerging growth company until the earlier of the last day of the fiscal year (i) following the fifth anniversary of the closing of our initial public offering, or July 6, 2026, (ii) in which we have total annual gross revenue of at least $1.235 billion or (iii) in which we are deemed to be a large accelerated filer, which means the market value of our common stock that is held by non-affiliates exceeds $700 million as of the prior June 30th, and the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the extended transition period to comply with new or revised accounting standards and to adopt certain of the reduced disclosure requirements available to

emerging growth companies. As a result of the accounting standards election, we will not be subject to the same implementation timing for new or revised accounting standards as other public companies that are not emerging growth companies, which may make comparison of our financials to those of other public companies more difficult. As a result of these elections, the information that we provide in this Annual Report on Form 10-K may be different than the information you may receive from other public companies in which you hold equity interests. In addition, it is possible that some investors will find our common stock less attractive as a result of these elections, which may result in a less active trading market for our common stock and higher volatility in our share price.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

Our management team may use our cash and cash equivalents in ways in which you may not agree or in ways which may not yield a return.

Our management has broad discretion over the use of our cash and cash equivalents. You will not have the opportunity to influence our decisions on how to use our cash and cash equivalents and will need to rely on our judgment with respect to the use of our cash and cash equivalents. The failure by our management to apply our cash and cash equivalents effectively could adversely affect our ability to continue maintaining and expanding our business.

We have never paid dividends on our capital stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. In addition, pursuant to our Loan Agreement, we are prohibited from paying cash dividends. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments.

Our failure to meet Nasdaq's continued listing requirements could result in a delisting of our common stock.

If we fail to satisfy Nasdaq's continued listing requirements, such as the corporate governance requirements or the minimum closing bid price requirement, Nasdaq may take steps to delist our common stock. Such a delisting would likely have a negative effect on the price of our common stock and would impair your ability to sell or purchase our common stock when you wish to do so. In the event of a delisting, we can provide no assurance that any action taken by us to restore compliance with listing requirements would allow our common stock to become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below the Nasdaq minimum bid price requirement or prevent future non-compliance with Nasdaq's listing requirements.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware and the U.S. federal district courts will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action asserting a breach of fiduciary duty;
- any claim or cause of action against us arising under the DGCL;
- any claim or cause of action arising under or seeking to interpret our amended and restated certificate of incorporation or our amended and restated bylaws; and
- any claim or cause of action against us that is governed by the internal affairs doctrine.

Further, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all such Securities Act actions. Accordingly, both state and federal courts have jurisdiction to entertain such claims. To prevent having to litigate claims in multiple jurisdictions and the threat of inconsistent or contrary rulings by different courts, among other considerations, our amended and restated certificate of incorporation will further provide that the U.S. federal district courts will be the exclusive forum for resolving any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to 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.

While the Delaware courts have determined that such choice of forum provisions are facially valid and several state trial courts have enforced such provisions and required that suits asserting Securities Act claims be filed in federal court, there is no guarantee that courts of appeal will affirm the enforceability of such provisions and, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated certificate of incorporation. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with litigating Securities Act claims in state court, or both state and federal court, which could seriously harm our business, financial condition, results of operations and prospects.

These exclusive forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees. If a court were to find either exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving the dispute in other jurisdictions, all of which could seriously harm our business.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;
- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we are not obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

General Risk Factors

We incur significant costs and demands upon management as a result of being a public company.

As a public company listed in the United States, we incur significant legal, accounting and other costs that could negatively affect our financial results. In addition, changing laws, regulations and standards relating to corporate governance and public disclosure, including regulations implemented by the SEC and Nasdaq, may increase legal and financial compliance costs and make some activities more time-consuming. These laws, regulations and standards are subject to varying interpretations and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies.

We intend to invest resources to comply with evolving laws, regulations and standards, and this investment may result in increased general and administrative expenses and a diversion of management's time and attention from revenue-generating activities to compliance activities. If, notwithstanding our efforts to comply with new laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us and our business may be harmed.

Failure to comply with these rules might also make it more difficult for us to obtain some types of insurance, including director and officer liability insurance, and we might be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, on committees of our board of directors or as members of senior management.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

We have generated net operating loss, or NOL, carryforwards during our history, we expect to continue to generate significant NOL carryforwards for the foreseeable future, and we may not achieve profitability prior to the time that certain of our NOL carryforwards expire. As of December 31, 2025, we had federal and state NOL carryforwards of $211.2 million and $96.5 million, respectively. Of the total federal NOLs of $211.2 million, $6.5 million will begin expiring in the year 2028 as will the state NOLs if not utilized. The remaining $204.7 million of federal NOL carryforwards as of December 31, 2025 do not expire due to the enactment of the Tax Cuts and Jobs Act of 2017, or the Tax Act, although are limited to 80% of taxable income annually. Our NOL carryforwards are subject to review and possible adjustment by U.S. and state tax authorities. Our NOL carryforwards could expire unused or be unavailable to offset future income tax liabilities because of their limited duration or because of restrictions under U.S. tax law. Federal NOL carryforwards generated in tax years ending on or prior to December 31, 2017 may only be carried forward for 20 taxable years under applicable U.S. federal tax law. Federal NOL carryforwards generated in tax years ending after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal NOL carryforwards is limited to 80% of current year taxable income. Similar rules may apply under state tax laws.

We may also qualify for business tax credits, such as research and development tax credits, which generally may be carried forward 20 years to offset a portion of future taxable income, if any, subject to expiration of such credit carryforwards. We have not determined the amount of credit carryforward recently due to the cost versus no current benefit of claiming the credit.

Additionally, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the IRC, if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "five-percent shareholders" that exceeds 50 percentage points over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards and certain other pre-change tax attributes (such as research and development tax credits) to offset its post-change income and taxes may be limited or eliminated. Similar rules may apply under state tax laws. The completion of our initial public offering, together with private placements and other transactions that have occurred since our inception, may have triggered such an ownership change pursuant to Section 382 or 383 of the IRC. We may experience ownership changes in the future as a result of subsequent shifts in our stock ownership, some of which may be outside our control. We have not conducted any studies to determine annual limitations, if any, that could result from such changes in the ownership. Our ability to utilize those NOL and credit carryforwards could be limited or eliminated by an "ownership change" as described above and consequently, we may not be able to utilize a material portion of our NOL carryforwards and certain other tax attributes, which could have an adverse effect on our cash flows and results of operations.

Changes in U.S. tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in U.S. tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisors regarding the implications of potential changes in U.S. tax laws on an investment in our common stock.

Disruptions at the FDA, the SEC and other government agencies caused by funding shortages, staff and workforce reductions or global health concerns could hinder the ability of these agencies to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those 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 may also slow the time necessary for new drugs or biologics to be reviewed and approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including from October 1, 2025 to November 12, 2025, the U.S. government has shut down several times, and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical FDA, SEC and other government employees and stop critical activities. If a prolonged government shutdown occurs or if the FDA's workforce is reduced further, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

If a prolonged government shutdown occurs, if the U.S. government takes certain personnel actions, or if global health concerns prevent the FDA or other comparable regulatory authorities from conducting business as usual or conducting inspections, reviews or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Unfavorable global economic conditions could adversely affect our business, financial condition or results of operations.

Our results of operations could be adversely affected by general conditions in the global economy and in the global financial markets. Portions of our clinical trials may be conducted outside of the United States and unfavorable economic conditions resulting in the weakening of the U.S. dollar would make those clinical trials more costly to operate. Further, a severe or prolonged economic downturn, including a recession or depression resulting from the national or international events or political disruption, such as the ongoing conflict between Russia and Ukraine, the recent military actions involving Iran or the Israel-Hamas war, could result in a variety of risks to our business, including weakened demand for our product candidates or any future product candidates, if approved, and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Item 1B. Unresolved Staff Comments.

None.

Item 1C. Cybersecurity.

Risk management and strategy.

We have adopted processes designed to identify, assess and manage material risks from cybersecurity threats. Those processes include frameworks to respond to and assess internal and external threats to the security, confidentiality and integrity of our data and information systems, along with other material risks to our operations, which we review at least annually or whenever there are material changes to our systems or operations.

Our IT department collaborates with our Chief Operating Officer to evaluate and address cybersecurity risks in alignment with our business objectives and operational needs. We have processes to detect potential vulnerabilities and anomalies through technical safeguards. As part of our risk management process, we conduct regular IT security audits to assess and respond to internal and external security threats. In addition, we consult with outside advisors and experts, when appropriate, to assist with assessing, identifying and managing cybersecurity risks, including to anticipate future threats and trends and their potential impact on the Company's risk environment.

We rely on third parties, including cloud vendors and consultants, for various business functions. We oversee third-party service providers by conducting vendor diligence. Vendors are generally assessed for risk based on the nature of their service, access to data and systems and supply chain risk and, based on that assessment, we conduct diligence that may include completing security questionnaires, onsite evaluation and scans or other technical evaluations.

Governance.

Our Board of Directors has established oversight mechanisms with respect to risks from cybersecurity threats. Our Audit Committee has primary responsibility for oversight of cybersecurity, including the responsibility to review and discuss with management and the Company's auditors, as appropriate, management risks relating to data privacy, technology and information security. The Audit Committee, or the Board of Directors as a whole, is briefed on any material cybersecurity incidents that may adversely affect the Company and on cybersecurity risks in general at least once each year.

At the management level, our cybersecurity program is managed by our Director of IT, who reports to our Chief Operating Officer. Our Director of IT has over 13 years of IT security experience in regulated industries such as government, energy and biopharma. He has over 20 years of combined IT experience.

Our Director of IT and IT Department implement processes around security monitoring and vulnerability testing. Our Director of IT reports at least annually to the Audit Committee and such reporting includes topics such as our risk assessment, risk management and control decisions, service provider arrangements, test results, security incidents and responses and recommendations for changes and updates to policies and procedures.

As of the date of this report, we have not experienced a cybersecurity incident that resulted in a material effect on our business strategy, results of operations or financial condition, but we cannot provide assurance that we will not be materially affected in the future by such risks or any future material incidents. For more information on cybersecurity risks, see Item 1A. Risk Factors—"Our business and operations would suffer in the event of computer system failures, cyberattacks or a deficiency in our cybersecurity or a natural disaster."

Item 2. Properties.

Our corporate headquarters are located in Newton, Massachusetts, where we lease approximately 3,758 square feet of office space pursuant to a 38-month lease, which commenced in October 2023. We also lease a small office in Towson, Maryland pursuant to a 12-month lease, which commenced in January 2026, and a small office in Charlottesville, Virginia, which is leased on a month-to-month basis. We believe that these facilities will be adequate for our near-term needs. If required, we believe that suitable additional or alternative space would be available in the future on commercially reasonable terms.

Item 3. Legal Proceedings.

From time to time, we may be involved in various claims and legal proceedings relating to claims arising out of our operations. We are not currently a party to any legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources and other factors.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

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

Market Information for Common Stock

Our common stock is listed on The Nasdaq Global Select Market under the symbol "ABOS."

Holders of Record

As of March 20, 2026, we had 70 holders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never paid cash dividends on any of our capital stock and currently intend to retain our future earnings, if any, to fund the development and growth of our business. In addition, our loan and security agreement with K2HV currently prohibits us from paying dividends on our equity securities, and any future debt agreements may likewise preclude us from paying dividends. See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Liquidity, Capital Resources and Going Concern."

Equity Compensation Plans

The information required by this item will be set forth in our 2026 Proxy Statement and is incorporated in this Annual Report on Form 10-K by reference.

Recent Sales of Unregistered Equity Securities

None.

Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and related notes appearing elsewhere in this Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our future results of operations or financial condition, business strategy and plans and objectives of management for future operations, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of important factors that could cause our actual results to differ materially from those described in or implied by these forward-looking statements contained in the following discussion and analysis.

Overview

We are a clinical-stage biopharmaceutical company developing a novel disease-modifying approach targeting what we believe to be a key underlying cause of Alzheimer's disease, or AD. Alzheimer's disease is a progressive neurodegenerative disease of the brain that leads to loss of memory and cognitive functions and ultimately results in death. Our scientific founders pioneered research on soluble amyloid-beta oligomers, or AßOs, which are globular assemblies of the amyloid-beta, or Aß, peptide that are distinct from Aß monomers and amyloid plaques. Based on decades of research and supporting evidence, AßOs have gained increasing scientific acceptance as a primary toxin involved in the initiation and propagation of AD pathology. We are currently focused on advancing a targeted immunotherapy drug candidate, sabirnetug, in our Phase 2 ALTITUDE-AD clinical trial, and expect to announce top-line results in late 2026. ALTITUDE-AD is a randomized, double-blind, placebo-controlled, three-arm clinical trial designed to evaluate the clinical efficacy, safety and tolerability of sabirnetug with up to 180 participants per arm for a total of 542 participants with mild cognitive impairment or mild dementia due to AD. We plan to use the Integrated Alzheimer's Disease Rating Scale at 18 months as the primary outcome measure. The active doses for ALTITUDE-AD are 35 mg/kg and 50 mg/kg, dosed intravenously every four weeks. These dose levels and frequency were selected based on extensive pharmacokinetic and pharmacodynamic modeling of our Phase 1 INTERCEPT-AD clinical trial of sabirnetug. Sabirnetug is a recombinant humanized immunoglobulin gamma 2, or IgG2, monoclonal antibody, or mAb, that was designed to selectively target AßOs. In July 2023, we announced topline results from INTERCEPT-AD, which demonstrated that sabirnetug met the primary and secondary objectives of this clinical trial in 62 participants with early AD.

We announced the results of a Phase 1 clinical trial investigating a subcutaneous dosing option of sabirnetug in March 2025. This study in healthy volunteers enrolled 16 subjects who received four weekly subcutaneous doses of 1,200 mg of sabirnetug and 12 subjects who received a single intravenous dose of 2,800 mg of sabirnetug. The most frequently reported adverse events included injection site reactions (62.5%), all of which were mild (Grade 1) in severity and resolved. No other safety issues were identified. Additionally, subcutaneous administration of sabirnetug was shown to produce sufficient systemic exposure to support further development of this formulation as a more convenient administration option for patients.

In addition, we are investigating a blood-brain barrier-penetrating, Aß oligomer-targeted Enhanced Brain Delivery (EBD™) therapy for AD. In March 2026, we announced certain preclinical data from EBD candidates, including *in vitro*, *in vivo* and non-human primate study results, supporting the advancement of the EBD program: (1) EBD candidates achieved 14-40x higher brain levels in non-human primates compared to native antibodies 24 hours after dosing; (2) hematology data in non-human primates indicated low potential for anemia, including that, at 24 hours after subcutaneous dosing, EBD candidates demonstrated no observed change in red blood cell count, hematocrit, hemoglobin or reticulocyte count; and (3) favorable stability profile and enhanced brain delivery support a path to subcutaneous administration with low-volume devices. Based on this data, an IND is targeted for mid-2027. In July 2025, we entered into a collaboration, option and license agreement with JCR Pharmaceuticals Co. Ltd., or JCR, to develop an Aß oligomer-targeted EBD™ therapy for the treatment of AD. Under the terms of the agreement, in addition to an upfront license payment that we paid to JCR, if we exercise our exclusive option to develop up to two development candidates, JCR will be eligible for an option exercise payment of $9.25 million. Our option is expected to be exercised when we have selected or identified up to two preclinical candidates we would license and advance into IND-enabling activities. JCR will also be eligible to receive future milestone payments of up to $40.0 million related to development, and up to $515.0 million related to sales, for a total of up to $555.0 million, as well as single-digit percentage royalties on sales of any products that emerge from the collaboration. The combination of sabirnetug or additional, novel, AβO-selective antibodies with JCR's blood-brain barrier-penetrating technology, J-Brain Cargo®, strengthens Acumen's portfolio of AβO-targeted therapies. The partnership is designed to advance potential next-generation treatment options for people living with AD, by targeting the development of products with enhanced efficacy, safety and convenience.

We were incorporated in 1996 and were party to an exclusive license and research collaboration with Merck & Co., Inc., or Merck, in 2003. Although we acquired the exclusive rights to sabirnetug from Merck in 2011 following Merck's strategic decision to focus its AD development efforts on a different product candidate, we did not recommence meaningful operations until we completed our first institutional fundraising in 2018. Since 2018, we have devoted substantially all of our efforts to organizing and staffing our company, business planning, raising capital, conducting discovery, research and development activities, and providing general and administrative support for these operations. We do not have any products approved for sale and have not generated any revenue from product sales. We have funded our operations primarily through the sale of our convertible preferred stock and common stock, the issuance of notes, entry into a term loan facility, grant revenue and, during our collaboration with Merck, certain payments received under our collaboration agreement.

In November 2023, we entered into a loan and security agreement, or the Loan Agreement, with K2 HealthVentures LLC, or, together with its affiliates, K2HV. The Loan Agreement provides us with a term loan facility in the aggregate principal amount of up to $50.0 million, of which we have borrowed $30.0 million in the first tranche and which was funded upon closing. The remaining $20.0 million is available for borrowing upon our request, subject to review by the lenders of certain information from us and discretionary approval by the lenders. The term loan facility matures on November 1, 2027 and can be extended to November 1, 2028, subject to our achievement of certain financing milestones. In accordance with the Loan Agreement, we issued to K2HV a warrant to purchase up to 730,769 shares of our common stock at an exercise price of $1.95 per share.

On March 13, 2026, we entered into a securities purchase agreement with certain institutional and accredited investors for a private placement, or the Private Placement, of 10,833,331 shares of our common stock, at an offering price of $3.30 per share. The Private Placement closed on March 16, 2026, for aggregate gross proceeds of approximately $35.75 million, before deducting applicable fees and expenses. We intend to use the net proceeds from the Private Placement to primarily support our EBD program, including ongoing preclinical development work to support the nomination of a lead clinical candidate molecule, and for working capital and other general corporate purposes.

During the year ended December 31, 2025, no shares of our common stock were issued under our at-the-market offering program, or the ATM. In January 2024, we issued 2,068,246 shares of our common stock under our ATM, for net proceeds of $7.9 million, or $3.84 per share.

We have incurred net losses and negative cash flows from operations since our inception. Our net losses were $121.3 million and $102.3 million for the years ended December 31, 2025 and 2024, respectively. Approximately $104.9 million, or 86%, of the net loss for the year ended December 31, 2025 was due to research and development spending. As of December 31, 2025, we had an accumulated deficit of $446.5 million and cash and cash equivalents and marketable securities of $116.9 million. We expect our expenses and operating losses will increase substantially for the foreseeable future as we advance sabirnetug in clinical development, seek to expand our product candidate portfolio through developing additional product candidates, and incur additional costs associated with operating as a public company. It is likely that we will seek third-party collaborators for the future commercialization of sabirnetug or any other product candidate that is approved for marketing. Should we seek to commercialize our products at our own expense, we would incur significant additional expenses for marketing, sales, manufacturing and distribution. We will not generate revenue from product sales unless and until we successfully complete clinical development and obtain regulatory approval for our product candidates.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity offerings and debt financings or other sources, such as potential collaboration agreements, strategic alliances and licensing arrangements. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on acceptable terms, or at all. In addition, global economic conditions may impact our ability to raise additional funds, and we may be impacted by disruptions to, and volatility in, the credit and financial markets in the United States and worldwide, tariff policy and geopolitical tensions between the United States and foreign countries, rising inflation and supply disruptions, the ongoing conflicts between Russia and Ukraine, the recent military actions involving Iran, and the Israel-Hamas war and related sanctions, and otherwise. If these conditions persist and deepen, we could experience an inability to access additional capital, or our liquidity could otherwise be impacted. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs and/or future commercialization efforts. Our failure to raise capital or enter into such agreements as and when needed could have a material adverse effect on our business, results of operations and financial condition.

We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. Based on our current operating plan, we expect that our current balance of cash and cash equivalents and marketable securities will fund our operations into early 2027, but we believe it will not be enough to fund our operations for at least 12 months from the date of issuance of our financial statements included in this Annual Report on Form 10-K. Our cash forecast contains estimates and assumptions related to our ongoing clinical trial and other research and development expenses, and we cannot predict the amount or timing of all expenditures with certainty. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern. See “Liquidity, Capital Resources and Going Concern.”

Components of Results of Operations

Operating Expenses

Our operating expenses consist of research and development expenses and general and administrative expenses.

Research and Development Expenses

Research and development costs primarily consist of direct costs associated with consultants and materials, biologic shipping and storage, third-party contract research organizations, or CROs, and contract manufacturing organizations, or CMOs, license agreements, salaries and other personnel-related expenses. Research and development costs are expensed as incurred. More specifically, these costs include:

- costs of funding research performed by third parties that conduct research and development and nonclinical and clinical activities on our behalf;
- costs of manufacturing drug supply and drug product;
- costs of conducting nonclinical studies and clinical trials of our product candidates;
- consulting and professional fees related to research and development activities, including noncash stock-based compensation to non-employees;
- payments made pursuant to our license agreements;
- costs related to compliance with clinical regulatory requirements; and
- employee-related expenses, including salaries, benefits and noncash stock-based compensation expenses for our research and development personnel.

As we currently only have one product candidate, sabirnetug, in clinical development, we do not separately track expenses by program. Further, we have historically relied primarily on consultants for research and development activities; our internal research and development personnel costs currently represent approximately 16% of our total research and development expenses. Our research and development expenses increased substantially since initiating the clinical trial program for sabirnetug in 2021. We expect that our research and development expenses will continue to increase substantially in connection with our continued clinical development activities for sabirnetug.

General and Administrative Expenses

General and administrative expenses consist primarily of employee-related expenses, including noncash stock-based compensation costs, as well as business insurance, management and business consultants and other related costs. General and administrative expenses also include professional fees for legal, consulting, accounting, auditing, tax, patent services, investor and public relations, board of directors’ expenses, information technology, franchise taxes, rent, travel expenses and subscriptions.

We expect that our general and administrative expenses will remain consistent for the foreseeable future and may increase as our organization and headcount required in the future grows to support continued research and development activities and potential commercialization of our product candidates. These increases will likely include increased costs related to the hiring of additional personnel and fees incurred for outside consultants, attorneys and accountants, among other expenses. Additionally, we expect to continue to incur significant expenses associated with being a public company, including costs of additional personnel, accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with exchange listing and Securities and Exchange Commission, or SEC, requirements, director and officer insurance costs, and investor and public relations costs.

Other Income (Expense)

Other income (expense) includes interest income, interest expense, change in fair value of embedded derivatives and other expense, net. Interest income consists of interest income earned, as well as amortization and accretion of premiums and discounts, related to our investments in marketable securities. Interest expense includes interest due under the Loan Agreement, as well as the amortization of the related debt discount. The change in fair value of embedded derivatives relates to the embedded derivatives that were bifurcated from the term loan, borrowed under the Loan Agreement, and accounted for as a derivative at fair value which is remeasured at each reporting period for the term of the loan. Other expense, net generally consists of fees incurred on our investments in marketable securities.

Results of Operations

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 (in thousands):

	Year Ended December 31,		Change	
	2025	2024	$	%
Operating expenses				
Research and development	$ 104,885	$ 93,798	$ 11,087	12 %
General and administrative	18,947	20,219	(1,272)	(6)%
Total operating expenses	123,832	114,017	9,815	9 %
Loss from operations	(123,832)	(114,017)	(9,815)	9 %
Other income (expense)				
Interest income	7,447	14,317	(6,870)	(48)%
Interest expense	(4,224)	(4,068)	(156)	4 %
Change in fair value of embedded derivatives	(460)	1,590	(2,050)	*
Other expense, net	(266)	(151)	(115)	76 %
Total other income	2,497	11,688	(9,191)	(79)%
Net loss	$ (121,335)	$ (102,329)	$ (19,006)	19 %

* Not meaningful

Research and Development Expenses

Research and development expenses were $104.9 million and $93.8 million for the years ended December 31, 2025 and 2024, respectively. The $11.1 million increase was primarily due to a $15.9 million increase for manufacturing and materials mainly associated with our ALTITUDE-AD clinical trial. Additionally, we incurred a $2.6 million increase for personnel-related costs, including share-based compensation expense, a $1.1 million increase for other research expenses including EBD research, a $0.6 million increase for shipping, packaging and storage costs, a $0.4 million increase for other clinical trial costs and $0.3 million for other expenses such as insurance and software. These increased expenses were partially offset by a decrease of $4.7 million for license agreement expense, a $2.3 million decrease in CRO costs associated with our ALTITUDE-AD clinical trial mainly due to pass through costs, a $1.6 million decrease related to services provided by research and development contractors and consultants and a $1.2 million decrease in clinical assay development work.

General and Administrative Expenses

General and administrative expenses were $18.9 million and $20.2 million for the years ended December 31, 2025 and 2024, respectively. The $1.3 million decrease was primarily due to $0.6 million for recruiting expense, $0.4 million for corporate insurance expense and $0.3 million for consulting costs.

Other Income (Expense)

Other income decreased by $9.2 million to $2.5 million for the year ended December 31, 2025 from $11.7 million for the year ended December 31, 2024. The decrease was primarily attributable to a $6.9 million decrease in interest income on our portfolio of marketable securities due to a lower average investment balance in marketable securities during the year

ended December 31, 2025. Additionally, there were increased expenses associated with the change in fair value of our embedded derivatives related to our Loan Agreement of $2.1 million. These decreases in other income were partially offset by an increase in interest expense of $0.2 million related to our Loan Agreement and other expense, net of $0.1 million.

Liquidity, Capital Resources and Going Concern

We have incurred net losses since inception. We have not generated any revenue from product sales or any other sources other than grant revenue and have incurred significant operating losses. We have not yet commercialized any products and we do not expect to generate revenue from sales of any drug candidates for at least several years, if ever.

Our operations have been financed primarily by net proceeds from the sale and issuance of our common stock and convertible preferred stock, net proceeds from our initial and subsequent public offering, the Private Placement and from sales of shares of our common stock under our ATM, borrowings under the Loan Agreement, the issuance of notes, grant revenue and, during our collaboration with Merck, which was in place from 2003 to 2011, certain payments received under our collaboration agreement.

On July 1, 2022, we filed a shelf registration statement on Form S-3, or the 2022 Registration Statement. Pursuant to the 2022 Registration Statement, we may offer and sell securities having an aggregate public offering price of up to $200.0 million.

In connection with the filing of the 2022 Registration Statement, we also entered into a sales agreement, or the Sales Agreement, with BofA Securities, Inc., or BofA, and Stifel, Nicolaus & Company, Incorporated, or Stifel, as sales agents, pursuant to which we may issue and sell shares of our common stock for an aggregate offering price of up to $50.0 million under the ATM, which was included in the $200.0 million of securities that were registered for sale pursuant to the 2022 Registration Statement. On April 23, 2023, we entered into an amendment to the Sales Agreement, or as amended, the Amended Sales Agreement, to add BTIG, LLC, or BTIG, as a sales agent under the Amended Sales Agreement. BTIG, BofA and Stifel are collectively referred to as the Sales Agents. Pursuant to the Amended Sales Agreement, we will pay the Sales Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of our common stock made under the ATM. We are not obligated to make any sales of shares of our common stock under the ATM.

On July 21, 2023, we issued 16,774,193 shares of our common stock in an underwritten public offering, or the Offering, at a price of $7.75 per share. The aggregate net proceeds from the Offering, after underwriting discounts and commissions and other offering expenses, were $121.9 million.

On November 10, 2023, we received the first tranche of $30.0 million under the Loan Agreement.

In January 2024, we issued 2,068,246 shares of common stock under the ATM for net proceeds of $7.9 million, or $3.84 per share. During the year ended December 31, 2025, no shares of our common stock were issued under our ATM.

On March 27, 2024, we filed a shelf registration statement on Form S-3, or the 2024 Registration Statement. Pursuant to the 2024 Registration Statement, we may offer and sell securities having an aggregate public offering price of up to $200.0 million. On November 13, 2025, we filed a prospectus supplement to the 2024 Registration Statement with respect to our ATM, designating up to $50.0 million of the $200.0 million of securities that may be offered pursuant to the 2024 Registration Statement for issuance under the ATM.

As of December 31, 2025, we had cash and cash equivalents and marketable securities totaling $116.9 million. Our available-for-sale marketable securities mature in less than one year. We could exhaust our available capital resources sooner than we expect, including if we decide to initiate other clinical trials or programs. We evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern. Based on our current operating plan, we expect that our current balance of cash and cash equivalents and marketable securities will fund our operations into early 2027, but we believe it will not be enough to fund our operations for at least 12 months from the date of issuance of our financial statements included in this Annual Report on Form 10-K. Accordingly, we have concluded that substantial doubt exists about our ability to continue as a going concern.

On March 13, 2026, we entered into a Private Placement of 10,833,331 shares of our common stock, at an offering price of $3.30 per share. The Private Placement closed on March 16, 2026, for aggregate gross proceeds of approximately $35.75 million, before deducting applicable fees and expenses. We intend to use the net proceeds from the Private Placement to

primarily support our EBD program, including ongoing preclinical development work to support the nomination of a lead clinical candidate molecule, and for working capital and other general corporate purposes.

We enter into contracts in the normal course of business with CROs and CMOs for clinical trials, nonclinical research studies and testing, manufacturing and other services and products for operating purposes. These contracts do not contain any minimum purchase commitments and are generally cancellable by us after giving a certain amount of notice. Payments due upon cancellation consist only of payments for services provided and expenses incurred up to the date of cancellation.

Cash Flows

The following table summarizes our sources and uses of cash (in thousands):

	Year Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (115,538)	$ (86,215)
Net cash provided by investing activities	133,933	48,027
Net cash (used in) provided by financing activities	(34)	6,928
Net change in cash and cash equivalents and restricted cash	$ 18,361	$ (31,260)

Operating Activities

The increase in net cash used in operating activities of $29.3 million to $115.5 million for the year ended December 31, 2025, from $86.2 million for the year ended December 31, 2024, is primarily attributable to an increase in net loss for the year ended December 31, 2025 of $19.0 million, a net increase in noncash adjustments of $6.4 million and working capital changes of $16.7 million. Significant noncash items consisted of decreases in noncash income for amortization and accretion on marketable securities of $4.2 million and the change in fair value of embedded derivatives of $2.0 million. Working capital changes contributed $16.7 million of additional cash used in operations, including increases in cash used for accrued clinical trial expenses and accounts payable of $15.7 million and $9.3 million, respectively, which were partially offset by cash provided by prepaid expenses and other current assets of $5.0 million and accrued expenses and other liabilities of $3.3 million.

Investing Activities

Net cash provided by investing activities increased by $85.9 million to $133.9 million for the year ended December 31, 2025 from $48.0 million for the year ended December 31, 2024, and was primarily due to a decrease in purchases of marketable securities of $132.7 million, partially offset by a decrease in cash provided by maturities of marketable securities of $46.7 million and an increase of $0.1 million for purchases of property and equipment.

Financing Activities

Net cash provided by financing activities during the year ended December 31, 2025 decreased by $7.0 million from cash provided by financing activities of $6.9 million for the year ended December 31, 2024. Cash provided by financing activities during the year ended December 31, 2024 was primarily due to net proceeds of $7.9 million from the issuance of common stock under our ATM, partially offset by $0.7 million for payment under a finance lease agreement for certain computer equipment for our Phase 2 ALTITUDE-AD clinical trial and $0.2 million for payments related to deferred offering costs.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue our research and development, conduct clinical trials and seek marketing approval for our current and any of our future product candidates. Furthermore, we expect to incur additional costs associated with operating as a public company. It is likely that we will seek third-party collaborators for the future commercialization of sabirnetug or any other product candidate that is approved for marketing. Should we seek to commercialize our products at our own expense, we would incur significant additional expenses for marketing, sales, manufacturing and distribution, which costs we may seek to offset through entry into collaboration agreements with third parties. As a result, we expect that we will need to obtain substantial additional

funding in connection with our future operations. If we are unable to raise capital when needed or on acceptable terms, we could be forced to delay, reduce or eliminate our research and development programs or future commercialization efforts.

Based on our current operating plan, we believe there is substantial doubt about our ability to continue as a going concern for at least 12 months following the date of issuance of our financial statements included in this Annual Report on Form 10-K. We could exhaust our available capital resources sooner than we expect, including if we decide to initiate other clinical trials or programs. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We may need to raise additional funds sooner than anticipated if we choose to expand more rapidly than we presently anticipate.

The amount and timing of our future funding requirements will depend on many factors, some of which are outside of our control, including but not limited to:

- the progress, costs, timing and results of ALTITUDE-AD and other potential clinical trials of sabirnetug, including for potential additional indications that we may pursue beyond AD;
- the requirements of the U.S. Food and Drug Administration, or the FDA, and European Medicines Agency, or EMA, and comparable foreign regulatory authorities, for clinical trials and nonclinical studies and other work, for review and approval of sabirnetug for AD;
- the outcome, costs and timing of seeking and obtaining FDA, EMA and any other regulatory approvals;
- our progress and success in investigating EBD™ therapy for AD;
- the number and characteristics of product candidates that we pursue;
- our ability to obtain sufficient quantities of our product candidates from our third-party manufacturers;
- our need to expand our research and development activities;
- the costs associated with securing and establishing commercialization capabilities if we were to elect to commercialize one or more products on our own;
- the economics and other terms, timing of and success of any collaboration, licensing or other arrangements into which we may enter for the commercialization of our products;
- the costs and other terms, timing and success, of acquiring, in-licensing or investing in businesses, product candidates and technologies;
- our ability to maintain, expand and defend the scope of our intellectual property portfolio, including the amount and timing of any payments we may be required to make, or that we may receive, in connection with the licensing, filing, prosecution, defense and enforcement of any patents or other intellectual property rights;
- our need and ability to retain management and hire scientific and clinical personnel;
- the effect of competing drugs and product candidates and other market developments; and
- our need to implement additional internal systems and infrastructure, including financial and reporting systems.

Additional funding may not be available to us on acceptable terms or at all. Any such funding may result in dilution to stockholders, imposition of debt covenants and repayment obligations or other restrictions that may affect our business. We also could be required to seek funds through arrangements with collaborative partners or otherwise that may require us to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us. Any funds we raise may not be sufficient to enable us to continue to implement our long-term business strategy. Further, our ability to raise additional capital may be adversely impacted by global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide, as well as tariff policy and geopolitical tensions between the United States and foreign countries. Additionally, escalation in interest rates, in conjunction with banking failures, may lead to financial institutions being more prudent with capital deployment and tightening lending. If we are unable to raise sufficient additional capital on a timely basis, we could be forced to curtail our planned operations and the pursuit of our business strategy, which would have a material adverse effect on the value of our common stock.

Critical Accounting Policies, Significant Judgments and Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles, or U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses incurred during the reporting periods. Our estimates and assumptions 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.

Actual results may differ from these estimates under different assumptions or conditions. We believe that the accounting policies discussed below are critical to understanding our historical and future performance, as these policies relate to the more significant areas involving management's judgments and estimates.

While our significant accounting policies are described in the notes to our financial statements included elsewhere in this Annual Report for Form 10-K, we believe that the following critical accounting policies are most important to understanding and evaluating our reported financial results.

Stock-Based Compensation Expense

We recognize stock-based compensation expense for all stock-based awards. Stock-based compensation costs are estimated at the grant date based on the fair value of the equity and recognized as expense, net of actual forfeitures when they occur, on a straight-line basis over the requisite service period.

We calculate the fair value of options using the Black-Scholes option-pricing model, which requires the use of various highly subjective assumptions as follows:

- *Expected Term*—We have opted to use the "simplified method" for estimating the expected term of options, whereby the expected term equals the arithmetic average of the mid-point between the vesting date and the end of contractual term of the option (generally 10 years).
- *Expected Volatility*—Prior to January 1, 2025, the Company lacked sufficient company-specific historical and implied volatility information for its common stock and estimated its expected stock volatility using a weighted average blend of historical volatility of a publicly traded set of peer companies, as well as its own historical volatility. Beginning on January 1, 2025, based on the availability of sufficient historical trading data of the Company's common stock, the Company began using its historical volatility.
- *Risk-Free Interest Rate*—The risk-free rate assumption is based on the U.S. Treasury yield in effect at the time of the grant with maturities consistent with the expected term of our options.
- *Expected Dividend Yield*—We have not issued any dividends in our history and do not expect to pay dividends on our common stock over the life of the options and therefore have estimated the dividend yield to be zero.

We will continue to use judgment in evaluating the expected volatility, expected terms and interest rates utilized for our stock-based compensation expense calculations on a prospective basis.

Accrued Research and Development Expenses

As part of the process of preparing our financial statements, we are required to estimate our accrued expenses as of each balance sheet date. This process involves reviewing open contracts and purchase orders, identifying services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of the actual cost. We make estimates of our accrued expenses as of each balance sheet date based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. The significant estimates in our accrued research and development expenses include the costs incurred for services performed by our vendors in connection with research and development activities for which we have not yet been invoiced. Since our inception, we have not experienced any material differences between accrued or prepaid costs and actual costs.

We base our expenses related to research and development activities on our estimates of the services received and efforts expended pursuant to quotes and contracts with vendors that conduct research and development on our behalf. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. There may be instances in which payments made to our vendors will exceed the level of services provided

and result in a prepayment of the research and development expense. In accruing service fees, we estimate the time period over which services will be performed and the level of effort to be expended in each period. If the actual timing of the performance of services or the level of effort varies from our estimate, we adjust the accrual or prepaid expense accordingly. Advance payments for goods and services that will be used in future research and development activities are expensed when the activity has been performed or when the goods have been received rather than when the payment is made.

Clinical trial costs are a significant component of accrued research and development expenses and include costs associated with third-party contractors. We accrue and expense costs for clinical trial activities performed by third parties based upon the work completed to date for each clinical trial in accordance with established agreements. Management determines costs through discussions with internal clinical stakeholders and outside service providers as to the progress or stage of completion of clinical trials or services and the contracted fee to be paid for such services. In the event advance payments are made to an outside service provider, the payments are recorded within prepaid expenses and other current assets in the balance sheet and subsequently recognized as research and development expense in the statement of operations and comprehensive loss when the associated services have been performed. As actual costs become known, we adjust our estimates, liabilities and assets. Inputs used in the determination of estimates discussed above may vary from actual, which will result in adjustments to research and development expense in future periods.

Embedded Derivatives

We evaluate embedded derivatives within convertible debt to determine whether the embedded derivatives should be bifurcated from the host instrument and accounted for as a derivative at fair value that will be remeasured at each reporting period for the term of the loan with changes in fair value recorded in the statements of operations and comprehensive loss. We initially assess the probability of the occurrence of trigger events for bifurcated embedded derivatives in determining fair value. The probability is reassessed at each reporting period during the term of a loan.

We calculate the fair value of embedded derivatives using the Monte Carlo option-pricing model, which requires the use of various highly subjective assumptions, including the expected term, expected volatility, risk-free interest rate and expected dividend yield.

Emerging Growth Company and Smaller Reporting Company Status

In April 2012, the Jumpstart Our Business Startups Act of 2012, or JOBS Act, was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. Thus, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We elected to use the extended transition period for complying with new or revised accounting standards, which delays the adoption of these accounting standards until they would apply to private companies.

In addition, as an emerging growth company, we may take advantage of specified reduced disclosure and other requirements that are otherwise applicable generally to public companies. These provisions include:

- an exception from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, as amended;
- reduced disclosure about our executive compensation arrangements in our periodic reports, proxy statements and registration statements;
- exemptions from the requirements of holding non-binding advisory votes on executive compensation or golden parachute arrangements; and
- an exemption from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor’s report on financial statements.

We may take advantage of these provisions until we no longer qualify as an emerging growth company. We will cease to qualify as an emerging growth company on the date that is the earliest of: (i) December 31, 2026, (ii) the last day of the fiscal year in which we have more than $1.235 billion in total annual gross revenues, (iii) the date on 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 that is held by non-affiliates exceeds $700 million as of the prior June 30th, or (iv) the date on which we have issued more than $1.0 billion of non-convertible debt over the prior three-year period. We may choose to take advantage of some but not all of these reduced reporting burdens. We have taken advantage of certain reduced reporting requirements in this Annual Report

on Form 10-K and our other filings with the SEC. Accordingly, the information contained herein may be different than you might obtain from other public companies in which you hold equity interests.

We are also a “smaller reporting company,” meaning that the market value of our shares held by non-affiliates is less than $700 million and our annual revenue was less than $100 million during the most recently completed fiscal year. We may continue to be a smaller reporting company if either (i) the market value of our shares held by non-affiliates is less than $250 million or (ii) our annual revenue is less than $100 million during the most recently completed fiscal year and the market value of our shares held by non-affiliates is less than $700 million. 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 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.

Not applicable to a smaller reporting company.

Item 8. Financial Statements and Supplementary Data.

ACUMEN PHARMACEUTICALS, INC.
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Report of Independent Registered Public Accounting Firm

To the Stockholders and the Board of Directors of Acumen Pharmaceuticals, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Acumen Pharmaceuticals, Inc. (the Company) as of December 31, 2025 and 2024, the related statements of operations and comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has suffered recurring losses from operations and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's 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 in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 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 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 financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.

Philadelphia, Pennsylvania
March 26, 2026

ACUMEN PHARMACEUTICALS, INC.
BALANCE SHEETS
(in thousands, except share and per share data)

	December 31,	
	2025	2024
ASSETS		
Current assets		
Cash and cash equivalents	$ 53,989	$ 35,627
Marketable securities, short-term	62,876	135,930
Prepaid expenses and other current assets	5,387	6,749
Total current assets	122,252	178,306
Marketable securities, long-term	—	59,968
Restricted cash	231	232
Other assets, long-term	350	486
Total assets	$ 122,833	$ 238,992
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 554	$ 5,648
Accrued clinical trial expenses	10,616	15,344
Accrued expenses and other current liabilities	10,072	6,615
Debt, short-term	8,765	—
Total current liabilities	30,007	27,607
Debt, long-term	22,396	29,419
Other liabilities, long-term	—	150
Total liabilities	52,403	57,176
Commitments and contingencies (Note 11)		
Stockholders' equity		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized and no shares issued and outstanding as of December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 300,000,000 shares authorized as of December 31, 2025 and 2024; 60,575,369 and 60,094,083 shares issued and outstanding as of December 31, 2025 and 2024, respectively	6	6
Additional paid-in capital	516,803	506,985
Accumulated deficit	(446,462)	(325,127)
Accumulated other comprehensive income (loss)	83	(48)
Total stockholders' equity	70,430	181,816
Total liabilities and stockholders' equity	$ 122,833	$ 238,992

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

ACUMEN PHARMACEUTICALS, INC.
STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	Year Ended December 31,	
	2025	2024
Operating expenses		
Research and development	$ 104,885	$ 93,798
General and administrative	18,947	20,219
Total operating expenses	123,832	114,017
Loss from operations	(123,832)	(114,017)
Other income (expense)		
Interest income	7,447	14,317
Interest expense	(4,224)	(4,068)
Change in fair value of embedded derivatives	(460)	1,590
Other expense, net	(266)	(151)
Total other income	2,497	11,688
Net loss	(121,335)	(102,329)
Other comprehensive gain (loss)		
Unrealized gain (loss) on marketable securities	131	(360)
Comprehensive loss	$ (121,204)	$ (102,689)
Net loss per common share, basic and diluted	$ (2.00)	$ (1.71)
Weighted-average shares outstanding, basic and diluted	60,561,836	60,013,277

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

ACUMEN PHARMACEUTICALS, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share data)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Accumulated Other Comprehensive Income (Loss)	Total Stockholders' Equity
	Shares	Amount				
Balance as of January 1, 2024	57,910,461	$ 6	$ 489,453	$ (222,798)	$ 312	$ 266,973
Issuance of common stock for cash, net of issuance costs of $87	2,068,246	—	7,938	—	—	7,938
Issuance of common stock for restricted stock units, net of shares withheld for taxes	115,376	—	(41)	—	—	(41)
Unrealized loss on marketable securities	—	—	—	—	(360)	(360)
Stock-based compensation	—	—	9,635	—	—	9,635
Net loss	—	—	—	(102,329)	—	(102,329)
Balance as of December 31, 2024	60,094,083	6	506,985	(325,127)	(48)	181,816
Issuance of common stock for restricted stock units, net of shares withheld for taxes	446,756	—	(73)	—	—	(73)
Stock options exercised for cash	34,530	—	39	—	—	39
Unrealized gain on marketable securities	—	—	—	—	131	131
Stock-based compensation	—	—	9,852	—	—	9,852
Net loss	—	—	—	(121,335)	—	(121,335)
Balance as of December 31, 2025	60,575,369	$ 6	$ 516,803	$ (446,462)	$ 83	$ 70,430

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

ACUMEN PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS
(in thousands)

	Year Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (121,335)	$ (102,329)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	58	63
Stock-based compensation expense	9,852	9,635
Amortization of premiums and accretion of discounts on marketable securities, net	(809)	(5,015)
Change in fair value of embedded derivatives	460	(1,590)
Amortization of right-of-use asset	126	115
Realized gain on marketable securities	(59)	(97)
Noncash interest expense	1,288	1,118
Other noncash expense	—	232
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	1,362	(3,656)
Other long-term assets	40	74
Accounts payable	(5,094)	4,269
Accrued clinical trial expenses	(4,728)	10,957
Accrued expenses and other liabilities	3,301	32
Finance lease liability	—	(23)
Net cash used in operating activities	(115,538)	(86,215)
Cash flows from investing activities		
Purchases of marketable securities	(38,056)	(170,731)
Proceeds from maturities and sales of marketable securities	172,077	218,774
Purchases of property and equipment	(88)	(16)
Net cash provided by investing activities	133,933	48,027
Cash flows from financing activities		
Proceeds from issuance of common stock, net of issuance costs	—	7,938
Proceeds from exercise of stock options	39	—
Payment for financing lease	—	(739)
Payments for deferred offering costs	—	(230)
Repurchase of common shares to pay employee withholding taxes	(73)	(41)
Net cash (used in) provided by financing activities	(34)	6,928
Net change in cash and cash equivalents and restricted cash	18,361	(31,260)
Cash and cash equivalents and restricted cash at the beginning of the period	35,859	67,119
Cash and cash equivalents and restricted cash at the end of the period	$ 54,220	$ 35,859

ACUMEN PHARMACEUTICALS, INC.
STATEMENTS OF CASH FLOWS (CONTINUED)
(in thousands)

	Year Ended December 31,	
	2025	2024
Supplemental disclosure of cash flow information		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ 2,936	$ 2,973

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

NOTE 1. DESCRIPTION OF ORGANIZATION AND BUSINESS OPERATIONS

Acumen Pharmaceuticals, Inc. ("Acumen" or the "Company") was incorporated in 1996 in the state of Delaware. Acumen is a clinical-stage biopharmaceutical company developing a novel disease-modifying approach targeting what the Company believes to be a key underlying cause of Alzheimer's disease ("AD"). Alzheimer's disease is a progressive neurodegenerative disease of the brain that leads to loss of memory and cognitive functions and ultimately results in death. The Company's scientific founders pioneered research on soluble amyloid-beta oligomers ("AßOs"), which are globular assemblies of the amyloid-beta ("Aß") peptide that are distinct from Aß monomers and amyloid plaques. Based on decades of research and supporting evidence, AßOs have gained increasing scientific acceptance as a primary toxin involved in the initiation and propagation of AD pathology. The Company is currently focused on advancing a targeted immunotherapy drug candidate, sabirnetug, in its Phase 2 ALTITUDE-AD clinical trial, and expects to announce top-line results in late 2026. ALTITUDE-AD is a randomized, double-blind, placebo-controlled, three-arm clinical trial designed to evaluate the clinical efficacy, safety and tolerability of sabirnetug with up to 180 participants per arm for a total of 542 participants with mild cognitive impairment or mild dementia due to AD. Sabirnetug is a recombinant humanized immunoglobulin gamma 2 monoclonal antibody that was designed to selectively target AßOs. In July 2023, the Company announced topline results from its Phase 1 INTERCEPT-AD clinical trial of sabirnetug, which demonstrated that sabirnetug met the primary and secondary objectives of this clinical trial in 62 participants with early AD. In addition, the Company is investigating a subcutaneous dosing option of sabirnetug, as well as a blood-brain barrier-penetrating, Aß oligomer-targeted Enhanced Brain Delivery (EBD™) therapy for AD.

The Company is subject to the uncertainty of whether its intellectual property will develop into successful commercial products.

Liquidity, Capital Resources and Going Concern

In accordance with Accounting Standards Codification ("ASC") 205-40, *Presentation of Financial Statements-Going Concern*, the Company evaluated whether there are conditions and events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern. The Company has incurred operating losses since inception. As of December 31, 2025, the Company had an accumulated deficit of $446.5 million and had cash and cash equivalents and marketable securities of $116.9 million. The Company expects to incur additional losses for the foreseeable future as it continues its research and development activities and will need to raise additional capital to fully implement its business plan and to fund its operations. Until such time, if ever, as the Company can generate revenue sufficient to achieve profitability, the Company expects to finance its operations through a combination of equity offerings, debt financings, collaborations, strategic alliances and licensing arrangements. There can be no assurance that any such financing will be available to the Company at adequate levels and on a timely basis, or such agreements may not be available on terms acceptable to the Company, or at all. The Company may be required to delay, limit, reduce or terminate its product discovery and development activities or future commercialization efforts if it is unable to maintain sufficient financial resources, and its business, financial condition and results of operations will be materially and adversely affected. The Company expects that its current balance of cash and cash equivalents and marketable securities may not be sufficient to fund its operations for at least 12 months from the date of issuance of these financial statements. The Company's cash forecast contains estimates and assumptions related to its ongoing clinical trial and other research and development expenses, and the Company cannot predict the amount or timing of all expenditures with certainty. Accordingly, the Company has concluded that substantial doubt exists about its ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business, and do not include any adjustments relating to recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary, should the Company be unable to continue as a going concern.

NOTE 2. BASIS OF PRESENTATION, SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES AND RECENT ACCOUNTING PRONOUNCEMENTS

Basis of Presentation

The accompanying financial statements of the Company have been prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and pursuant to the rules and regulations of the U.S.

Securities and Exchange Commission ("SEC"). In the opinion of management, all adjustments (consisting of normal recurring adjustments) have been made that are necessary to present fairly the Company's financial position, and the results of its operations and its cash flows.

Emerging Growth Company

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial statements upon adoption. Under the Jumpstart Our Business Startups Act of 2012, as amended, the Company meets the definition of an emerging growth company and has elected to use the extended transition period for complying with new or revised accounting standards, which delays the adoption of these accounting standards until they would apply to private companies.

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 and disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported amounts of expenses during the reporting periods. These estimates and assumptions are based on the Company's historical experience, and on various other factors that management believes are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities and the recording of expenses that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions. To the extent there are material differences between the estimates and actual results, the Company's future results of operations will be affected. The more significant estimates and assumptions by management include, among others: the valuation allowance of deferred tax assets resulting from net operating losses, the valuation of stock options, the valuation of embedded derivatives within the Company's debt, long-term and accruals for clinical trial expenses and other research and development expenses.

Cash and Cash Equivalents and Restricted Cash

The Company considers all highly liquid investments with an original maturity of three months or less at the date of purchase to be cash equivalents. All of the Company's cash equivalents have liquid markets and high credit ratings. The Company had $53.7 million and $35.3 million in cash equivalents as of December 31, 2025 and 2024, respectively.

Restricted cash primarily consists of deposited cash collateral for the Company's credit card program.

The following table provides a reconciliation of cash, cash equivalents and restricted cash from the balance sheets to the statements of cash flows (in thousands):

	December 31,	
	2025	2024
Cash and cash equivalents	$ 53,989	$ 35,627
Restricted cash	231	232
Total cash, cash equivalents and restricted cash	$ 54,220	$ 35,859

Marketable Securities

The Company's marketable securities portfolio consists primarily of investments in money market funds, U.S. treasury and agency securities and short-term highly liquid, high credit quality corporate debt securities. The Company considers its marketable securities to be available-for-sale. Available-for-sale securities are classified as cash equivalents, or as short-term or long-term marketable securities based on the maturity date at the time of purchase and their availability to meet current operating requirements. Available-for-sale securities that mature in three months or less from the date of purchase are classified as cash equivalents. Available-for-sale securities, excluding cash equivalents, that mature in one year or less are classified as short-term marketable securities and those that mature in more than one year are classified as long-term.

Securities that are classified as available-for-sale are measured at fair value; see "*Fair Value of Financial Instruments*" below. Any premium arising at purchase is amortized to the earliest call date and any discount arising at purchase is accreted to maturity. Amortization of premiums and accretion of discounts are recorded along with interest income on investments in interest income, net in the statements of operations and comprehensive loss. Unrealized gains and losses are excluded from earnings and are reported as a component of other comprehensive income. The cost of investments sold will be calculated using the specific-identification method.

For securities available-for-sale, Accounting Standards Update 2016-13, *Financial Instruments-Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments* eliminates the concept of other-than-temporary impairment and instead requires entities to determine if impairment is related to credit loss or non-credit loss. In making the assessment of whether a loss is from credit or other factors, management considers the extent to which fair value is less than amortized cost, any changes to the rating of the security by a rating agency and adverse conditions related to the security, among other factors. If this assessment indicates that a credit loss exists, the present value of cash flows expected to be collected from the security are compared to the amortized cost basis of the security. If the present value of cash flows is less than the amortized cost basis, a credit loss exists and an allowance is created, limited by the amount that the fair value is less than the amortized cost basis. Subsequent activity related to the credit loss component in the form of write-offs or recoveries is recognized as part of the allowance for credit losses on securities available-for-sale. The Company has made the accounting policy election to exclude accrued interest receivable on securities from the estimate of credit losses and will record a credit loss expense for accrued interest receivable in the period when a credit loss is recorded for the related securities.

Management determined that the Company did not require an allowance for credit losses for available-for-sale securities as of December 31, 2025 or 2024, as the aggregate amount of any credit losses was immaterial. The Company did not have any related write-offs or recoveries for the years ended December 31, 2025 and 2024.

Concentrations of Credit Risk

Financial instruments that potentially subject the Company to significant concentration of credit risk consist primarily of cash, cash equivalents and marketable securities. The Company maintains deposits in financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk as the Company's cash and cash equivalents are held at financial institutions that management believes to be of high credit quality. The Company has not experienced any losses due to credit risk on such accounts during any of the periods presented.

Fair Value of Financial Instruments

The Company's financial assets and liabilities are accounted for in accordance with ASC 820, *Fair Value Measurements and Disclosures*, which defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The fair value hierarchy requires an entity to maximize the use of observable inputs when measuring fair value and classifies those inputs into three levels:

Level 1 — Observable inputs, such as quoted prices in active markets for identical assets or liabilities.

Level 2 — Inputs other than Level 1 inputs that are either directly or indirectly observable, 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 instrument's anticipated life.

Level 3 — Unobservable inputs in which there is little or no market data, which require the reporting entity to develop its own assumptions.

To the extent the valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair values requires more judgment. Accordingly, the degree of judgment exercised by management in determining fair value is greatest for instruments categorized as Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. There were no transfers made among the three levels in the fair value hierarchy for the years ended December 31, 2025 and 2024.

The carrying values reported in the balance sheets for cash (excluding cash equivalents which are recorded at fair value on a recurring basis), restricted cash, accounts payable, accrued clinical trial expenses and accrued expenses are reasonable estimates of their fair values due to the short-term nature of these items.

The carrying amount of the Company's long-term debt approximates fair value due to its variable market interest rate and management's opinion that current rates and terms that would be available to the Company with the same maturity and security structure would be essentially equivalent to that of the Company's long-term debt. Certain features of the Company's term loan facility (the "Term Loan") were determined to be an embedded derivative requiring separate measurement from the loan host instrument. For additional information regarding the Term Loan, see *Note 6. Debt*.

Property and Equipment

Property and equipment are stated at cost. Depreciation expense is computed using the straight-line method over the estimated useful lives of the assets, including leasehold improvements and finance lease right-of-use assets that are amortized over the shorter of their estimated useful lives or the terms of the respective leases. The Company generally uses the following useful lives for its property and equipment categories: three years for computer-related assets and five years for furniture. *See Note 5. Supplemental Financial Information.*

Leases

The Company accounts for its leases under ASC 842, *Leases*. Under this guidance, arrangements meeting the definition of a lease are classified as operating or finance leases and are recorded in the balance sheet at the commencement date as both a right-of-use asset and a lease liability, calculated by discounting fixed lease payments over the lease term at the rate implicit in the lease or the Company's incremental borrowing rate. Lease liabilities are increased by interest and reduced by payments each period, and right-of-use assets are amortized over the lease term, or, for finance leases, over the shorter of the lease term or the estimated useful life of the assets. For operating leases, interest on the lease liability and the amortization of the right-of-use asset results in straight-line rent expense over the lease term. For finance leases, the right-of-use asset is amortized on a straight-line basis and the amortization is presented as an operating expense separately from interest expense on the lease liability. Variable lease expenses are recorded when incurred and not included in the measurement of right-of-use assets and lease liabilities.

ASC 842 provides practical expedients for an entity's ongoing accounting. In calculating right-of-use assets and lease liabilities, the Company has elected to combine lease and non-lease components for real estate leases, but has not elected to combine lease and non-lease components for computer equipment leases. Additionally, the Company has elected not to recognize a right-of-use asset or lease liability for leases with an initial term of 12 months or less. For short-term leases, the Company recognized lease payments on a straight-line basis over the lease term.

Computer Equipment Lease

In September 2023, the Company entered into an agreement with a vendor that included the lease of certain computer equipment for its Phase 2 clinical trial with an October 2023 lease commencement date. In January 2024, the Company paid $0.8 million for the computer equipment, which will be returned to the vendor at the completion of the vendor's services under the agreement. Upon the lease inception, the Company recorded noncash expense of $0.7 million in research and development expense in the statement of operations and comprehensive loss for the right-of-use assets related to the computer equipment lease as the equipment is being used for research and development and does not have an alternative future use.

Debt Discount and Debt Issuance Costs

The debt discount, which reduces the related debt balance in the balance sheets, is comprised of debt issuance costs, contractual fees due upon repayment of the debt, the issuance date fair value of warrants issued with the debt and the issuance date fair value of any derivatives that are bifurcated from the debt. Debt issuance costs include direct costs (e.g., legal costs and bank fees) incurred to issue non-revolving debt instruments. The debt discount is amortized to interest expense over the contractual term of the related debt using the effective interest method.

Embedded Derivatives

The Company evaluates embedded derivatives within debt to determine whether the embedded derivatives should be bifurcated from the host instrument and accounted for as a derivative at fair value that will be remeasured at each reporting period for the term of the loan, with changes in fair value recorded in the statements of operations and comprehensive loss. Management initially assesses the probability of the occurrence of trigger events for bifurcated embedded derivatives in determining fair value. The probability is reassessed at each reporting period during the term of a loan.

Research and Development Expenses

Research and development ("R&D") expenses primarily consist of consultants and materials, biologic storage, salaries and other personnel-related expenses related to R&D activities and are expensed as incurred. Payments for these activities are based on the terms of the individual agreements, which may differ from the pattern of costs incurred, and are reflected on the balance sheets as prepaid or accrued expenses. The Company records accruals for estimated ongoing research costs. When evaluating the adequacy of the accrued liabilities, the Company analyzes progress of the studies or research, including the phase or completion of events, invoices received and contracted costs.

Clinical trial costs are a significant component of R&D expenses and include costs associated with third-party contractors. The Company accrues and expenses costs for clinical trial activities performed by third parties based upon the work completed to date for each clinical trial in accordance with established agreements. The Company determines its costs through discussions with internal clinical stakeholders and outside service providers as to the progress or stage of completion of clinical trials or services and the contracted fee to be paid for such services. In the event advance payments are made to an outside service provider, the payments are recorded within prepaid expenses and other current assets in the balance sheets and subsequently recognized as R&D expense in the statements of operations and comprehensive loss when the associated services have been performed. As actual costs become known, the Company adjusts its estimates, liabilities and assets. Inputs used in the determination of estimates discussed above may vary from actual, which will result in adjustments to R&D expense in future periods.

The Company has acquired licenses of intellectual property to develop and commercialize product candidates. Upfront payments that relate to licenses of intellectual property, as well as pre-commercial milestone payments, are immediately expensed as acquired in-process research and development in the period in which they are incurred, provided that the licenses did not also include processes or activities that would constitute a "business" as defined under U.S. GAAP and have no established alternative future use.

Stock-based Compensation

The Company expenses stock-based compensation to employees, non-employees and board members over the requisite service period based on the estimated grant date fair value of the awards and actual forfeitures. The Company estimates the fair value of stock option grants using the Black-Scholes option pricing model, which requires the use of a number of complex assumptions including expected volatility, risk-free interest rate, expected dividends, and the expected term of the option. The fair value of restricted stock units ("RSUs") is the closing market price of the common stock on the date of the grant. The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. Stock-based awards with graded-vesting schedules are recognized on a straight-line basis over the requisite service period. All stock-based compensation costs are recorded in research and development expense or general and administrative expense in the statements of operations and comprehensive loss based upon the respective employee's or non-employee's roles within the Company. Forfeitures are recorded as they occur. See *Note 8. Stock-based Compensation.*

Income Taxes

Income taxes are recorded in accordance with ASC 740, *Income Taxes* ("ASC 740"), which provides for deferred taxes using an asset and liability approach. The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Deferred tax assets and liabilities are determined based on the difference between the financial statement and tax bases of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse, and net operating loss ("NOL") carryforwards and R&D tax credit carryforwards. Valuation allowances are provided if, based upon the weight of available

evidence, it is more likely than not that some or all of the deferred tax assets will not be realized. The Company has recorded a full valuation allowance to reduce its net deferred income tax assets to zero. In the event the Company were to determine that it would be able to realize some or all of its deferred income tax assets in the future, an adjustment to the deferred income tax asset valuation allowance would increase income in the period such determination was made.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit would more likely than not be realized assuming examination by the taxing authority. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. The Company has not recorded any liabilities related to uncertain tax positions as of December 31, 2025 and 2024. The Company's policy is to record interest and penalties, if any, as part of income tax benefit. No interest or penalties were recorded during the years ended December 31, 2025 and 2024.

Net Loss Per Share of Common Stock

Basic net loss per share of common stock is computed by dividing net loss by the weighted-average number of shares of common stock outstanding during the period. Diluted net loss per share of common stock includes the effect, if any, from the potential exercise or conversion of securities, such as convertible debt, stock options, RSUs and warrants, which would result in the issuance of incremental shares of common stock. However, potential shares of common stock are excluded if their effect is anti-dilutive. For diluted net loss per share, the weighted-average number of shares of common stock is the same for basic net loss per share due to the fact that when a net loss exists, dilutive securities are not included in the calculation as the impact is anti-dilutive. For the years ended December 31, 2025 and 2024, potential common shares consisted of stock options, RSUs, convertible debt and a warrant to purchase common stock.

Potentially dilutive securities not included in the calculation of diluted net loss per share of common stock as of the periods presented, because to do so would be anti-dilutive, were as follows:

	December 31,	
	2025	2024
Shares issuable upon exercise of stock options	12,578,766	10,656,129
Shares issuable upon conversion election for Term Loan	988,142	988,142
Shares issuable upon exercise of warrant	730,769	730,769
Unvested RSUs	1,907,976	1,354,543
Total	16,205,653	13,729,583

Segment Information

Operating segments are defined as components of an enterprise for which separate discrete financial information is available for evaluation by the chief operating decision maker ("CODM") in deciding how to allocate resources and assess performance. The Company's CODM is its chief executive officer. The Company has one operating segment focused on the research and development of sabirnetug for the treatment of patients with AD. *See Note 10 – Segments.*

Collaboration Agreements

The Company enters into collaboration agreements with companies to license intellectual property and may be obligated to make future development, regulatory and commercial milestone payments and royalty payments on future sales of specified products associated with these agreements. Payments under these agreements generally become due and payable upon achievement of such milestones or sales. These commitments are not recorded on the Company's balance sheet because the achievement and timing of these milestones are not fixed and determinable. When the achievement of these milestones or sales has occurred, the corresponding amounts are recognized in the Company's financial statements.

Recently Adopted Accounting Pronouncements

In December 2023, the FASB issued Accounting Standards Update ("ASU") 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures.* The standard is intended to enhance the existing income tax disclosures to

provide information to better assess how an entity's operations and related tax risks and tax planning and operational opportunities affect its tax rate and prospects for future cash flows. The standard was adopted by the Company on a prospective basis for its annual period beginning on January 1, 2025. The adoption of this standard did not have a material impact on the Company's financial statements and disclosures.

Recently Issued Accounting Pronouncements

In November 2024, the FASB issued ASU 2024-04, *Debt - Debt with Conversion and Other Options (Subtopic 470- 20): Induced Conversions of Convertible Debt Instruments.* The standard is intended to clarify the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion. The standard is effective for annual periods beginning after December 15, 2025, and for interim periods within those annual reporting periods. Early adoption is permitted if ASU 2020-06 has been adopted. As of December 31, 2025, the Company had no induced conversions. The Company will adopt this standard on a prospective basis on January 1, 2026 and does not expect this standard to have any impact on its financial statements upon adoption.

In November 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses.* The standard is intended to require more detailed disclosures about specified categories of expenses, including employee compensation, depreciation and amortization, included in certain expense captions presented on the face of the income statement. The ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 31, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is evaluating the potential impact of this adoption on the financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-11, *Interim Reporting - Narrow Scope Improvements.* The standard is intended to improve the guidance in Topic 270, Interim Reporting, by improving the navigability of the required
interim disclosures and clarifying when that guidance is applicable. The amendments in this update clarify interim disclosure requirements and the applicability of Topic 270. The amendments also provide additional guidance on what disclosures should be provided in interim reporting periods. The amendments in this update are effective for interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. Upon adoption, the amendments may be applied on a prospective or retrospective basis. The Company is evaluating the potential impact of this adoption on the financial statements and related disclosures.

NOTE 3. MARKETABLE SECURITIES

The Company's marketable securities consisted of the following (in thousands):

	December 31, 2025			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale securities, short-term				
Corporate debt securities	$ 62,793	$ 88	$ (5)	$ 62,876
Total available-for-sale securities, short-term	$ 62,793	$ 88	$ (5)	$ 62,876

	December 31, 2024			
	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Fair Value
Available-for-sale securities, short-term				
Corporate debt securities	$ 118,813	$ 128	$ (8)	$ 118,933
Government and agency - U.S. securities	16,962	35	—	16,997
Total available-for-sale securities, short-term	135,775	163	(8)	135,930
Available-for-sale securities, long-term				
Corporate debt securities	60,171	—	(203)	59,968
Total available-for-sale securities, long-term	60,171	—	(203)	59,968
Total available-for-sale securities	$ 195,946	$ 163	$ (211)	$ 195,898

The following tables summarize the amount of unrealized losses, defined as the amount by which the amortized cost exceeds fair value, and the related fair value of available-for-sale marketable securities with unrealized losses, which have been segregated into two categories: those that have been in a continuous unrealized loss position for less than 12 months and those that have been in a continuous unrealized loss position for 12 or more months (in thousands):

	December 31, 2025					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 6,036	$ (3)	$ 5,119	$ (2)	$ 11,155	$ (5)
Total	$ 6,036	$ (3)	$ 5,119	$ (2)	$ 11,155	$ (5)

	December 31, 2024					
	Less than 12 Months		Greater than 12 Months		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt securities	$ 73,952	$ (211)	$ 2,515	$ —	$ 76,467	$ (211)
Total	$ 73,952	$ (211)	$ 2,515	$ —	$ 76,467	$ (211)

As of December 31, 2025, the Company's available-for-sale securities mature in one year or less. As noted in the tables above, some of the Company's available-for-sale marketable securities have been in an unrealized loss position for more than 12 months as of December 31, 2025 and 2024. The unrealized loss as of December 31, 2025 is immaterial and the Company does not intend to sell any of its available-for-sale securities and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost bases, which may be at maturity. No credit losses were recognized on the Company's available-for-sale securities during the years ended December 31, 2025 and 2024. The Company recorded realized gains of approximately $0.1 million during each of the years ended December 31, 2025 and December 31, 2024.

NOTE 4. FAIR VALUE MEASUREMENTS

The Company's financial assets and liabilities subject to fair value measurement on a recurring basis and the level of inputs used for such measurements were as follows (in thousands):

	Fair value measurements as of December 31, 2025 using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value as of December 31, 2025
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 53,708	$ —	$ —	$ 53,708
Marketable securities				
Corporate debt securities	—	62,876	—	62,876
Total fair value	$ 53,708	$ 62,876	$ —	$ 116,584
Liabilities included in:				
Debt, long-term				
Embedded derivative liabilities	$ —	$ —	$ 1,430	$ 1,430
Total fair value	$ —	$ —	$ 1,430	$ 1,430

	Fair value measurements as of December 31, 2024 using			
	Quoted Prices in Active Markets for Identical Assets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	Fair Value as of December 31, 2024
Assets included in:				
Cash and cash equivalents				
Money market securities	$ 35,268	$ —	$ —	$ 35,268
Marketable securities				
Corporate debt securities	—	178,901	—	178,901
Government and agency - U.S.	—	16,997	—	16,997
Total fair value	$ 35,268	$ 195,898	$ —	$ 231,166
Liabilities included in:				
Debt, long-term				
Embedded derivative liabilities	$ —	$ —	$ 970	$ 970
Total fair value	$ —	$ —	$ 970	$ 970

The fair value of the Company's money market funds is determined using quoted market prices in active markets for identical assets.

The fair value for the available-for-sale marketable securities is determined based on valuation models using inputs that are observable either directly or indirectly (Level 2 inputs), such as quoted prices for similar assets or liabilities, yield curve, volatility factors, credit spreads, default rates, loss severity, current market and contractual prices for the underlying instruments or debt, broker and dealer quotes, as well as other relevant economic measures.

The following table presents changes in Level 3 liabilities measured at fair value for the two-year period ended December 31, 2025 (in thousands):

Balance, January 1, 2024	$ 2,560
Change in fair value of embedded derivatives	(1,590)
Balance, December 31, 2024	970
Change in fair value of embedded derivatives	460
Balance, December 31, 2025	$ 1,430

NOTE 5. SUPPLEMENTAL FINANCIAL INFORMATION

Prepaid expenses and other assets as of December 31, 2025 and 2024 consisted of the following (in thousands):

	December 31, 2025		
	Prepaid Expenses and Other Current Assets	Other Long-Term Assets	Total Prepaid Expenses and Other Assets
Research and development service agreements	$ 3,527	$ 29	$ 3,556
Other receivables	625	—	625
Prepaid insurance	601	—	601
Dues and subscriptions	368	—	368
Right-of-use asset	—	140	140
Property and equipment, net (1)	—	103	103
Other	266	78	344
Total	$ 5,387	$ 350	$ 5,737

	December 31, 2024		
	Prepaid Expenses and Other Current Assets	Other Long-Term Assets	Total Prepaid Expenses and Other Assets
Research and development service agreements	$ 4,841	$ 75	$ 4,916
Prepaid insurance	858	—	858
Other receivables	345	—	345
Dues and subscriptions	230	—	230
Right-of-use asset	—	266	266
Property and equipment, net (1)	—	73	73
Other	475	72	547
Total	$ 6,749	$ 486	$ 7,235

(1) As of December 31, 2025 and 2024, accumulated depreciation totaled approximately $0.2 million and $0.1 million, respectively.

Accrued expenses and other current liabilities as of December 31, 2025 consisted of the following (in thousands):

	Accrued Expenses and Other Current Liabilities
Research and development	$ 5,427
Compensation and other employee liabilities	4,066
Interest	249
Operating lease liability	150
Other	180
Total	$ 10,072

Accrued expenses and other liabilities as of December 31, 2024 consisted of the following (in thousands):

	December 31, 2024		
	Accrued Expenses and Other Current Liabilities	Other Long-Term Liabilities	Total Accrued Expenses and Other Liabilities
Compensation and other employee liabilities	$ 4,207	$ —	$ 4,207
Research and development	1,796	—	1,796
Interest	249	—	249
Operating lease liability	133	150	283
Other	230	—	230
Total	$ 6,615	$ 150	$ 6,765

NOTE 6. DEBT

Term Loan

On November 10, 2023, the Company entered into a Loan and Security Agreement with K2 HealthVentures LLC (the “Loan Agreement”). The Loan Agreement provided the Company with a Term Loan in the aggregate principal amount of $50.0 million, of which the Company borrowed $30.0 million in the first tranche upon closing. The remaining $20.0 million is available for borrowing upon the Company’s request based on review of certain information and discretionary approval from the lenders. The principal amount of the Term Loan outstanding under the Loan Agreement bears interest per annum at the greater of (i) 9.65% or (ii) the sum of the prime rate last quoted in The Wall Street Journal plus 1.15% for such interest period. The Term Loan matures on November 1, 2027, and can be extended to November 1, 2028 if the Company achieves certain financing milestones. The Loan Agreement provides for a final payment fee of an additional $1.6 million (the “Final Payment”) due upon repayment of the Term Loan. As security for its obligations under the Loan Agreement, the Company granted the lenders a security interest in substantially all of the Company’s assets (other than intellectual property).

The principal and interest of the Term Loan are to be repaid in equal monthly installments beginning on July 1, 2026 through the maturity of the Loan Agreement. The Loan Agreement allows prepayment of the entire Term Loan or a portion of the Term Loan of more than $5.0 million, provided that any partial prepayment will leave outstanding borrowings of at least $15.0 million.

The lenders can elect to convert up to $2.5 million of the Term Loan (the “Conversion Amount”) into the Company’s common stock at a conversion price of $2.53 (the “Conversion Option”). If the lenders elect to convert the Conversion Amount upon the Next Qualified Financing, as defined in the Loan Agreement whereby the Company receives aggregate gross proceeds of at least $20.0 million, the conversion price will equal the lowest effective cash price per share of securities issued in such Qualified Financing (the “Share-Settled Redemption”). The Conversion Option and Share-Settled Redemption within the Loan Agreement are required to be bifurcated as a single compound embedded derivative (the

"Embedded Derivatives") at fair value, with subsequent changes in fair value recognized in the statements of operations and comprehensive loss.

In accordance with the Loan Agreement, the Company issued an equity-classified warrant to purchase 730,769 shares of common stock (the "Loan Warrant"), with an initial allocated fair value of $1.1 million. See additional discussion in *Note 7. Stockholders' Equity.*

The initial recognition of the direct fees of $0.5 million, the Final Payment of $1.6 million, the fair value of the Embedded Derivatives at issuance of the Term Loan of $1.2 million and the fair value of the Loan Warrant of $1.1 million for the Loan Agreement resulted in a discount of $4.4 million, which is being amortized to interest expense over the term of the Loan Agreement using the effective interest method.

Outstanding debt consisted of the following (in thousands):

	December 31,	
	2025	2024
Principal value of Term Loan, including final payment of $1,635	$ 31,635	$ 31,635
Fair value of bifurcated embedded derivatives	1,430	970
Unamortized debt discount	(1,904)	(3,186)
Total	31,161	29,419
Less: debt, short-term	8,765	—
Total debt, long-term	$ 22,396	$ 29,419

The following table provides the components of interest expense (in thousands):

	Year Ended December 31,	
	2025	2024
Interest expense based on the coupon interest rate of the outstanding debt	$ 2,935	$ 2,943
Accretion of debt discount	1,282	1,112
Total interest expense related to debt	$ 4,217	$ 4,055

For the years ended December 31, 2025 and 2024, the effective interest rate for the Term Loan was 14.1% and 13.5%, respectively.

As of December 31, 2025, the aggregate principal payments due for the Term Loan by year are as follows (in thousands):

Year ended December 31, 2026	$ 10,104
Year ended December 31, 2027	21,531
Total principal payment due for Term Loan	$ 31,635

NOTE 7. STOCKHOLDERS' EQUITY

Authorized Shares

As of December 31, 2025, the total number of shares of capital stock authorized to be issued per the Company's Amended and Restated Certificate of Incorporation is 310,000,000, with 10,000,000 shares designated as preferred stock with a par value of $0.0001, and 300,000,000 shares designated as common stock, with a par value of $0.0001. Each share of common stock issued and outstanding is entitled to one vote.

Shelf Registration and At-The-Market Equity Offering

On July 1, 2022, the Company filed a shelf registration statement on Form S-3 (the "2022 Registration Statement"). Pursuant to the 2022 Registration Statement, the Company may offer and sell securities having an aggregate public offering price of up to $200.0 million.

In connection with the filing of the 2022 Registration Statement, the Company also entered into a sales agreement (the "Sales Agreement") with BofA Securities, Inc. ("BofA") and Stifel, Nicolaus & Company, Incorporated ("Stifel") as sales agents, pursuant to which the Company may issue and sell shares of its common stock for an aggregate offering price of up to $50.0 million under an at-the-market offering program (the "ATM"), which was included in the $200.0 million of securities that were registered for sale pursuant to the 2022 Registration Statement. On April 23, 2023, the Company entered into an amendment to the Sales Agreement (as amended, the "Amended Sales Agreement") to add BTIG, LLC ("BTIG") as a sales agent under the Amended Sales Agreement (BTIG, BofA and Stifel are collectively referred to as the "Sales Agents"). Pursuant to the Amended Sales Agreement, the Company will pay the Sales Agents a commission rate of up to 3.0% of the gross proceeds from the sale of any shares of the Company's common stock made under the ATM. The Company is not obligated to make any sales of shares of its common stock under the ATM.

During the year ended December 31, 2025, the Company did not sell any shares of common stock under the ATM. During the year ended December 31, 2024, the Company issued and sold 2,068,246 shares of common stock under the ATM for net proceeds of $7.9 million, or $3.84 per share. The Company has issued shares of common stock for aggregate gross proceeds of $12.2 million under the ATM since the program's inception.

On March 27, 2024, the Company filed a shelf registration statement on Form S-3 (the "2024 Registration Statement"). Pursuant to the 2024 Registration Statement, the Company may offer and sell securities having an aggregate public offering price of up to $200.0 million. On November 13, 2025, the Company filed a prospectus supplement to the 2024 Registration Statement with respect to its ATM, designating up to $50.0 million of the $200.0 million of securities that may be offered pursuant to the 2024 Registration Statement for issuance under the ATM.

Restricted Stock Units

During the years ended December 31, 2025 and 2024, the Company issued 446,756 and 115,376 shares, respectively, of its common stock in settlement of fully vested RSUs.

Common Stock Warrant

On November 10, 2023, in accordance with the Loan Agreement, the Company issued the Loan Warrant to purchase 730,769 shares of its common stock at an exercise price of $1.95 with a ten-year contractual term and an allocated fair value of $1.1 million. This warrant is outstanding as of December 31, 2025. In accordance with ASC 815, the Loan Warrant issued in 2023 did not meet the definition of a derivative and was classified in stockholders' equity in the balance sheet.

NOTE 8. STOCK-BASED COMPENSATION

2021 Equity Incentive Plan

The 2021 Equity Incentive Plan (the "2021 Plan"), which provides for the grant of incentive stock options to employees, and the grant of nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock units, performance awards and other forms of stock awards to employees, directors and consultants, became effective on June 30, 2021. The 2021 Plan is a successor to the Company's Amended and Restated Stock Performance Plan that was adopted by the Company's board of directors and stockholders on April 8, 2013 (as amended from time to time, most recently on November 20, 2020, the "2013 Plan"). Following the effectiveness of the 2021 Plan, no further grants may be made under the 2013 Plan; however, any outstanding equity awards granted under the 2013 Plan continue to be governed by the 2013 Plan. As of December 31, 2025, there were 3,129,483 options outstanding under the 2013 Plan.

The number of shares of common stock reserved for issuance under the 2021 Plan automatically increases on January 1 of each calendar year through January 1, 2031, in an amount equal to 5% of the total number of shares of common stock outstanding on December 31 of the fiscal year before the date of each automatic increase, or a lesser number of shares

determined by the board of directors prior to the applicable January 1. On January 1, 2025, the number of shares of common stock reserved for issuance under the 2021 Plan automatically increased by 3,004,704 shares.

The maximum number of shares of common stock that may be issued upon the exercise of incentive stock options under the 2021 Plan is 12,000,000. As of December 31, 2025, 17,673,425 shares were authorized for issuance under the 2021 Plan and 2,344,000 shares remained available for issuance under the 2021 Plan.

The Company recorded stock-based compensation expense related to stock options and RSUs in the following expense categories of the statements of operations and comprehensive loss for the periods shown (in thousands):

	Year Ended December 31,	
	2025	2024
General and administrative	$ 5,913	$ 6,113
Research and development	3,939	3,522
Total stock-based compensation	$ 9,852	$ 9,635

Stock Options

The Black-Scholes option-pricing model was used to estimate the fair value of stock options granted during the years ended December 31, 2025 and 2024 with the following weighted average assumptions:

	Year Ended December 31,	
	2025	2024
Risk-free interest rate	3.8% – 4.5%	3.8% – 5.1%
Expected term (in years)	1.0 – 6.0	0.9 – 6.1
Expected volatility	76% - 92%	92% - 103%
Expected dividend yield	0%	0%

The weighted average grant date fair value of options granted during the years ended December 31, 2025 and 2024 was $1.26 per share and $2.85 per share, respectively.

Stock options granted after December 31, 2017 generally vest monthly over a range of 12 to 48 months or vest monthly over a total of 48 months following a one-year cliff and all have a ten-year contractual term. Beginning January 1, 2024, stock options granted to consultants vest quarterly over a one-year period, provided the consultants continue to perform services as dictated by their respective consulting agreements with the Company. Annual option awards issued to members of the Company's board of directors vest in full on the first anniversary of the grant date. Stock options granted prior to December 31, 2017 were either fully vested upon grant or generally vested monthly over a range of three to 24 months and have a ten-year term. The Company's common stock became publicly traded in July 2021. Prior to January 1, 2025, the Company lacked sufficient company-specific historical and implied volatility information for its common stock and estimated its expected stock volatility using a weighted average blend of historical volatility of a publicly traded set of peer companies, as well as its own historical volatility. Beginning on January 1, 2025, based on the availability of sufficient historical trading data of the Company's common stock, the Company began using its historical volatility to estimate expected stock volatility. Due to the lack of historical exercise history, the expected term of the Company's stock options has been determined using the "simplified" method for awards. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected

term of the award. Expected dividend yield is zero based on the fact that the Company has never paid cash dividends and does not expect to pay any cash dividends in the foreseeable future.

The following table reflects summarized stock option activity during the year ended December 31, 2025:

	Stock Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2024	10,656,129	$ 3.83		
Granted	2,188,960	$ 1.64		
Exercised	(34,530)	$ 1.13		
Forfeited	(75,402)	$ 2.75		
Expired	(156,391)	$ 4.23		
Outstanding as of December 31, 2025	12,578,766	$ 3.46	7.0	$ 374
Vested and exercisable as of December 31, 2025	8,421,358	$ 3.66	6.2	$ 346

The intrinsic value of stock options exercised during the year ended December 31, 2025 was immaterial. There were no stock options exercised during the year ended December 31, 2024. As of December 31, 2025, total unrecognized compensation cost related to unvested stock option awards granted was approximately $9.4 million, which the Company expects to recognize over a weighted-average period of approximately 2.2 years.

Restricted Stock Units

RSUs granted to employees vest in equal annual installments on the first three anniversaries of the grant date and RSUs granted to members of the Company's board of directors vest in full on the first anniversary of the grant date.

The following table reflects summarized RSU activity during the year ended December 31, 2025:

	Number of Shares	Weighted Average Grant Date Fair Value
Unvested as of December 31, 2024	1,354,543	$ 4.46
Granted	1,066,950	$ 1.73
Vested	(485,867)	$ 4.57
Forfeited	(27,650)	$ 2.31
Unvested as of December 31, 2025	1,907,976	$ 2.93

As of December 31, 2025, total unrecognized compensation cost related to unvested RSUs was approximately $2.8 million, which the Company expects to recognize over a weighted-average period of approximately 1.5 years.

Employee Stock Purchase Plan

The 2021 Employee Stock Purchase Plan (the "ESPP"), which permits employees to purchase shares of common stock, became effective on June 30, 2021. The number of shares of common stock reserved for issuance automatically increases on January 1 of each calendar year through January 1, 2031, by the lesser of (1) 1% of the total number of shares of common stock outstanding on the last day of the fiscal year before the date of the automatic increase, and (2) 800,000 shares; provided, however, that before the date of any such increase, the board of directors may determine that such increase will be less than the amount set forth in clauses (1) and (2). On January 1, 2025, the number of shares of common stock reserved for issuance under the ESPP automatically increased by 600,941 shares. As of December 31, 2025, there are a total of 2,370,029 shares reserved for issuance under the ESPP and there have been no purchases of shares under the ESPP, as the ESPP has not yet been implemented.

NOTE 9. INCOME TAXES

The Company has not recorded any tax provision or benefit for federal income taxes for the years ended December 31, 2025 and 2024. Current income taxes are based upon the year's income taxable for federal and state tax reporting purposes. Deferred income taxes (benefits) are provided for certain income and expenses, which are recognized in different periods for tax and financial reporting purposes. Deferred tax assets and liabilities are computed for differences between the financial statements and tax bases of assets and liabilities that will result in taxable or deductible amounts in the future based on enacted tax laws and rates applicable to the period in which the differences are expected to affect taxable income, and NOL and R&D tax credit carryforwards.

A reconciliation of the U.S. statutory federal income tax rate of 21% to the Company's effective income tax rate, after the adoption of ASU 2023-09 for the year ended December 31, 2025 is as follows:

	Year Ended December 31, 2025	
	Amount	Percent
Statutory federal income tax rate	$ (25,453)	21.0 %
Non-deductible stock compensation	1,222	(1.0)
Other	432	(0.4)
Change in valuation allowance	23,799	(19.6)
Income tax provision	$ —	— %

A reconciliation of the U.S. statutory federal income tax rate of 21% to the Company's effective income tax rate, prior to the adoption of ASU 2023-09 for the year ended December 31, 2024 is as follows:

	Year Ended December 31, 2024
Statutory federal income tax rate	21.0 %
State tax, net of federal benefit	3.1 %
Non-deductible stock compensation	(0.5)%
Rate change	0.4 %
Other	(1.9)%
Change in valuation allowance	(22.1)%
Income tax provision	— %

Significant components of the Company's deferred tax assets as of December 31, 2025 and 2024 were as follows (in thousands):

	December 31,	
	2025	2024
Deferred tax assets:		
Net operating loss	$ 50,390	$ 20,906
Capitalized R&D	27,657	29,548
Stock compensation	4,179	3,171
R&D credit	992	1,215
Intangible assets	622	443
Accruals and other temporary differences	1,796	1,395
Gross deferred tax assets	85,636	56,678
Valuation allowance	(85,473)	(56,405)
Total deferred tax assets	163	273
Deferred tax liabilities:		
Embedded debt derivative liabilities	(128)	(208)
Other	(35)	(65)
Total deferred tax liabilities	(163)	(273)
Net deferred tax assets	$ —	$ —

In assessing the realizability of deferred tax assets as of December 31, 2025 and 2024, management considered whether it is more likely than not that some portion or all of the deferred tax assets will be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which those temporary differences become deductible or the net operating loss ("NOL") carryforwards and R&D tax credit carryforwards will be used. The Company has determined that it is not more likely than not that its deferred tax assets will be realized. Accordingly, a valuation allowance for the full amount of the net deferred tax assets has been recorded as of December 31, 2025 and 2024. The change in the valuation allowance as of December 31, 2025 from December 31, 2024 is due to the pretax loss incurred for the year ended December 31, 2025.

As of December 31, 2025, the Company had approximately $211.2 million of NOL carryforwards available for federal tax purposes. As a result of the Tax Act of 2017, for U.S. income tax purposes, NOLs generated prior to December 31, 2017 can still be carried forward for up to 20 years, but NOLs generated after December 31, 2017 carryforward indefinitely, but are limited to 80% utilization against taxable income. Of the total federal NOLs of $211.2 million, $6.5 million will begin to expire on December 31, 2028 and $204.7 million will not expire.

As of December 31, 2025, the Company also had approximately $96.5 million of state NOL carryforwards. The state NOLs begin to expire on December 31, 2028.

As of December 31, 2025, the Company had approximately $1.0 million of R&D credit carryforwards available for federal tax purposes, which begin to expire on December 31, 2026.

Utilization of the NOL and R&D credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that may have occurred or that could occur in the future, as required by Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), as well as similar state provisions. These ownership changes may limit the amount of NOL and R&D credit carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an "ownership change" as defined by Section 382 of the Code results from a transaction or series of transactions over a three-year period resulting in an ownership change of more than 50% of the outstanding stock of a company by certain stockholders.

The Company has not completed a formal analysis of the potential impact of Section 382 on its deferred tax assets as of December 31, 2025. Until this analysis has been completed, the Company has not adjusted any of its deferred tax assets,

including NOLs or R&D credits. The Company will reassess the amount of NOLs and credits subject to limitation under Section 382 when a study is complete. Due to the existence of the valuation allowance, future changes in the deferred tax assets related to these tax attributes will not impact the Company's effective tax rate.

The Company is subject to U.S. federal and various state taxes. Generally, the tax years remain open for examination by the federal statute under a three-year statute of limitation; however, states generally keep their statutes open for four years. However, the Company's tax years from 2004 and after are subject to examination by the United States and state taxing authorities due to the carry forward of unused NOLs and R&D credits.

NOTE 10. SEGMENT REPORTING

The Company manages its operations as a single segment. The CODM assesses performance and allocates resources for its clinical-stage biopharmaceutical segment based on net loss, which is reported on the statement of operations and comprehensive loss as net loss. The CODM is regularly provided with actual, budgeted and forecasted expense information to make decisions on resource allocation and assess performance of the business and monitor budget versus actual results using loss from operations. Substantially all long-lived assets are located in the U.S. The measure of segment assets is reported on the balance sheet as total assets.

The following table presents selected financial information about the Company's single operating segment for the years ended December 31, 2025 and 2024 (in thousands):

	Year Ended December 31,	
	2025	2024
Operating expenses		
Research and development		
External costs	$ 81,909	$ 71,188
Internally-managed costs (1)	19,028	19,062
General and administrative (2)	12,985	14,069
Other segment expenses (3)	9,910	9,698
Other income, net	(2,497)	(11,688)
Segment net loss	$ 121,335	$ 102,329

(1) Includes Company-managed research, consultants and contractors, as well as internal personnel and operating expenses, and excludes stock-based compensation expense and depreciation.
(2) Excludes stock-based compensation expense and depreciation.
(3) Other segment expenses include stock-based compensation expense and depreciation.

NOTE 11. COMMITMENTS AND CONTINGENCIES

The Company is not a party to any material legal proceedings and is not aware of any pending or threatened claims. From time to time, the Company may be subject to various legal proceedings and claims that arise in the ordinary course of its business activities.

In July 2025, the Company entered into a collaboration, option and license agreement with JCR Pharmaceuticals Co. Ltd. ("JCR") to develop an Aß oligomer-targeted Enhanced Brain Delivery (EBD™) therapy for the treatment of AD. Under the terms of the agreement, the Company paid JCR an upfront license payment, which was recognized as in-process research and development expense during the year ended December 31, 2025. Additionally, if the Company exercises its exclusive option to develop up to two development candidates, JCR will be eligible to receive an option exercise payment of $9.25 million. JCR will also be eligible to receive future milestone payments of up to $40.0 million related to development, and up to $515.0 million related to sales, for a total of up to $555.0 million, as well as single-digit percentage royalties on sales of any products that emerge from the collaboration.

In November 2023, the Company entered into a Non-exclusive Collaboration and License Agreement (the "Halozyme License Agreement") with Halozyme, Inc. ("Halozyme"). Under the terms of the Halozyme License Agreement, Halozyme

granted the Company a non-exclusive license to Halozyme's drug delivery technology for the development of a subcutaneous formulation of sabirnetug (such combination, the "Halozyme Product"). In January 2024, the Company paid a seven-figure upfront license payment for the Halozyme Product. The Company is required to make milestone payments upon the achievement of certain development and commercialization events with respect to the Halozyme Product, as well as milestone payments based on achievement of certain net sales levels of the Halozyme Product. The Company will also make single-digit royalty payments based on worldwide net sales of the Halozyme Product. The upfront license payment and milestones are recorded as in-process research and development expense when incurred.

In November 2022, the Company entered into a License Agreement ("Lonza License Agreement") with Lonza Sales AG ("Lonza"). Under the terms of the Lonza License Agreement, Lonza granted the Company a worldwide-non-exclusive license to use Lonza's glutamine synthetase gene expression system to manufacture and commercialize sabirnetug (the "Lonza Product"). Under the terms of the Lonza License Agreement, in consideration of the licenses and consents granted to the Company, the Company paid an upfront fee of 1.0 million Swiss Francs. The Company is also required to pay certain royalties upon commercialization and annual payments on a country-by-country basis in respect of the manufacturing and sale of the Lonza Product, which include (i) a royalty of less than 1% on net sales where Lonza manufactures the Lonza Product, (ii) an annual royalty payment in Swiss Francs in the low six-digits and a royalty of less than 1% on net sales where the Company manufactures the Lonza Product and (iii) an annual payment in Swiss Francs in the mid six-digits per sublicense and a royalty on net sales in the low single digits where a third party manufactures the Lonza Product. These payment obligations expire ten years from the first commercial sales of the Lonza Product in such country of sale.

NOTE 12. SUBSEQUENT EVENTS

In January 2026, the Company issued 727,052 shares of its common stock in settlement of fully vested RSUs. The Company also issued 77,006 shares of its common stock in connection with the exercise of stock options subsequent to year end.

On March 13, 2026, the Company entered into a securities purchase agreement with certain institutional and accredited investors for a private placement (the "Private Placement") of 10,833,331 shares of the Company's common stock, at an offering price of $3.30 per share. The Private Placement closed on March 16, 2026, for aggregate gross proceeds of approximately $35.75 million, before deducting applicable fees and expenses. The Company intends to use the net proceeds from the Private Placement to primarily support its EBD program, including ongoing preclinical development work to support the nomination of a lead clinical candidate molecule, and for working capital and other general corporate purposes.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to our management, including our principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of December 31, 2025. Based on the evaluation of our disclosure controls and procedures, our management concluded that, as of December 31, 2025, our disclosure controls and procedures were effective to provide reasonable assurance that the information required to be disclosed by us in this Annual Report on Form 10-K was (i) reported within the time periods specified by SEC rules and regulations, and (ii) communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding any 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 Rule 13a-15(f) and 15d-15(f) under the Exchange Act, as a process designed by, or under the supervision of, our principal executive and principal financial and accounting officers and effected by our board of directors and management 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 (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with U.S. GAAP, and that receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on our financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with policies or procedures may deteriorate. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2025. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in the original Internal Control—Integrated Framework updated in 2013. Based on that assessment, our management concluded that our internal control over financial reporting was effective as of December 31, 2025.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended December 31, 2025 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Attestation Report on Internal Control over Financial Reporting

This Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm on internal control over financial reporting as we are not subject to Section 404(b) of the Sarbanes-Oxley Act due to our status as a "smaller reporting company" and "non-accelerated filer."

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Insider Trading Policies and Procedures

We have an insider trading policy which governs the purchase, sale and/or other dispositions of the Company's securities by the Company's directors, employees, related persons and other covered persons, and is designed to promote compliance with insider trading laws, rules and regulations and listing standards applicable to the Company. The Company's insider trading policy is included as an exhibit to this Annual Report on Form 10-K. Our insider trading policy does not apply directly to repurchases of securities by the Company, but we have not made repurchases of our securities to date and do not reasonably expect to be in a position to repurchase our securities in the near future. If we were to repurchase our securities, we expect to follow the policy's guidelines in connection with securities repurchases by effecting trades either during open window periods under the policy or through adoption, during an open window period, of a pre-arranged trading plan that satisfies the affirmative defense requirements of Rule 10b5-1 under the Exchange Act.

The other information required by this item will be contained in our 2026 Proxy Statement, to be filed with the SEC not later than 120 days after the end of our fiscal year ended December 31, 2025, under the captions "Information Regarding the Board of Directors and Corporate Governance," "Election of Directors" and "Executive Officers" and is incorporated in this report by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in the 2026 Proxy Statement under the captions "Executive Compensation" and "Director Compensation" and is incorporated herein by reference.

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

The information required by this item will be set forth in the 2026 Proxy Statement under the captions "Security Ownership of Certain Beneficial Owners and Management" and "Equity Compensation Plan Information" and is incorporated herein by reference.

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

The information required by this item will be set forth in the 2026 Proxy Statement under the captions "Transactions with Related Persons and Indemnification" and "Independence of the Board of Directors" and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this item will be set forth in the 2026 Proxy Statement under the caption "Ratification of Selection of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibit and Financial Statement Schedules.

(a)(1) Financial Statements

The financial statements are included in Item 8. "Financial Statements and Supplementary Data."

(a)(2) Financial Statement Schedules

All schedules are omitted as information required is inapplicable or the information is presented in the financial statements and the related notes.

(a)(3) Exhibits

Exhibit Number	Description of Exhibit
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40551), filed with the Securities and Exchange Commission on June 8, 2023).
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 15, 2023).
4.1	Description of the Company's Common Stock (incorporated by reference to Exhibit 4.2 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 28, 2022).
10.1†	License Agreement, by and between the Registrant and Lonza Sales AG, dated November 2, 2022 (incorporated by reference to Exhibit 10.1 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 27, 2023).
10.2†	Collaboration Agreement, by and between the Registrant and Merck & Co., Inc., dated December 22, 2003, as amended and restated as of October 18, 2006 (incorporated by reference to Exhibit 10.1 to the Company's Registration Statement on Form S-1/A (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.3+	2021 Equity Incentive Plan and Forms of Option Grant Notice and Agreement, Exercise Notice, Early Exercise Notice and Restricted Stock Award Notice (incorporated by reference to Exhibit 10.2 to the Company's Registration Statement on Form S-1/A (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.4*+	Amended and Restated Non-Employee Director Compensation Policy
10.5+	2021 Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.4 to the Company's Registration Statement on Form S-1/A (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).
10.6+	2013 Amended and Restated Stock Performance Plan (as amended through November 20, 2020) (incorporated by reference to Exhibit 10.5 to the Company's Registration Statement on Form S-1 (File No. 333-256945), filed with the Securities and Exchange Commission on June 9, 2021).
10.7+	Form of Indemnification Agreement with Executive Officers and Directors (incorporated by reference to Exhibit 10.6 to the Company's Registration Statement on Form S-1/A (File No. 333-256945), filed with the Securities and Exchange Commission on June 24, 2021).

Exhibit Number	Description of Exhibit
10.8+	Amended and Restated Executive Employment Agreement, by and between the Registrant and Daniel O'Connell (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 28, 2022).
10.9+	Amended and Restated Executive Employment Agreement, by and between the Registrant and Matthew Zuga (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 28, 2022).
10.10+	Executive Employment Agreement, by and between the Registrant and James Doherty (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40551), filed with the Securities and Exchange Commission on May 13, 2025).
10.11	Lease, by and between Registrant and DIV Washington, LLC, dated September 11, 2023 (incorporated by reference to Exhibit 10.13 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 26, 2024).
10.12	Non-Exclusive Collaboration and License Agreement, by and between the Registrant and Halozyme, Inc., dated November 5, 2023 (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 26, 2024).
10.13	Loan and Security Agreement by and among the Registrant and the lenders party thereto, K2 Health Ventures LLC, as administrative agent, and Ankura Trust Company, LLC, as collateral agent, dated as of November 10, 2023 (incorporated by reference to Exhibit 10.15 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 26, 2024).
10.14	Collaboration, Option, and License Agreement by and between the Company and JCR Pharmaceuticals Co., Ltd., dated July 15, 2025 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q (File No. 001-40551), filed with the Securities and Exchange Commission on August 12, 2025).
19.1	Amended and Restated Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 27, 2025).
23.1*	Consent of Ernst & Young LLP, independent registered accounting firm.
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 Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1#	Certification of Principal Executive Officer 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 Principal 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	Policy for Recoupment of Incentive Compensation (incorporated by reference to Exhibit 97.1 to the Company's Annual Report on Form 10-K (File No. 001-40551), filed with the Securities and Exchange Commission on March 26, 2024).
101.INS*	Inline XBRL Instance Document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.

Exhibit Number	Description of Exhibit
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 (embedded within the Inline XBRL document).

* Filed herewith.

† Pursuant to Item 601(b)(10) of Regulation S-K, certain confidential portions of this exhibit have been omitted by means of marking such portions with asterisks [***] as the identified confidential portions (i) are not material and (ii) the Registrant customarily and actually treats that information as private or confidential.

\+ Indicates management contract or compensatory plan.

\# These certifications are being furnished solely to accompany this annual report pursuant to 18 U.S.C. Section 1350, and are not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and are not to be incorporated by reference into any filing of the registrant, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

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.

ACUMEN PHARMACEUTICALS, INC.

Date: March 26, 2026

By: /s/ Daniel O'Connell
Daniel O'Connell
Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Daniel O'Connell, William Matthew Zuga and Derek Meisner, and each of them, as his or her true and lawful agents, proxies and attorneys-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities to sign this Annual Report on Form 10-K of Acumen Pharmaceuticals, Inc., and any or all amendments thereto, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents full power and authority to do and perform each and every act and thing requisite or necessary to be done in and about the premises hereby ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Daniel O'Connell Daniel O'Connell	Chief Executive Officer and Director *(Principal Executive Officer)*	March 26, 2026
/s/ William Matthew Zuga William Matthew Zuga	Chief Financial Officer and Chief Business Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 26, 2026
/s/ Kimberlee C. Drapkin Kimberlee C. Drapkin	Director	March 26, 2026
/s/ Nathan B. Fountain Nathan B. Fountain, M.D.	Director	March 26, 2026
/s/ George Golumbeski George Golumbeski, Ph.D.	Director	March 26, 2026
/s/ Jeffrey L. Ives Jeffrey L. Ives, Ph.D.	Director	March 26, 2026
/s/ Derrell D. Porter Derrell D. Porter, M.D.	Director	March 26, 2026
/s/ Sean Stalfort Sean Stalfort	Director	March 26, 2026
/s/ Laura Stoppel Laura Stoppel, Ph.D.	Director	March 26, 2026

Exhibit 10.4

Acumen Pharmaceuticals, Inc.

Non-Employee Director Compensation Policy

Originally Adopted by the Board of Directors: Effective June 30, 2021

Amended by the Board of Directors: March 24, 2022

Amended by the Board of Directors: March 6, 2025

Amended by the Board of Directors: March 24, 2026

Each member of the Board of Directors (the "***Board***") who is not also serving as an employee of Acumen Pharmaceuticals, Inc. (the "***Company***") or any of its subsidiaries (each such member, an "***Eligible Director***") will receive the compensation described in this Non-Employee Director Compensation Policy for his or her Board service, in all cases subject to the limitations on annual non-employee director compensation set forth in the Company's 2021 Equity Incentive Plan (as it may be amended from time to time, the "***Plan***") or any successor thereto. An Eligible Director may decline all or any portion of his or her compensation by giving notice to the Company prior to the date cash may be paid or equity awards are to be granted, as the case may be. This policy may be amended at any time in the sole discretion of the Board or the Compensation Committee of the Board.

Annual Cash Compensation

Effective as of June 3, 2026 (the "***Effective Date***"), the annual cash compensation amount set forth below is payable to Eligible Directors in equal quarterly installments, payable in arrears on the last day of each fiscal quarter in which the service occurred or upon the earlier resignation or removal of the Eligible Director. If an Eligible Director joins the Board or a committee of the Board at a time other than effective as of the first day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal quarter, with the pro-rated amount paid on the last day of the first fiscal quarter in which the Eligible Director provides the service and regular full quarterly payments thereafter. If an Eligible Director resigns or is removed from the Board at a time other than effective as of the last day of a fiscal quarter, each annual retainer set forth below will be pro-rated based on days served in the applicable fiscal quarter. All annual cash fees are vested upon payment.

1. Annual Board Service Retainer:
    a. All Eligible Directors: $40,000
    b. Non-Executive Chairman: $30,000
    c. Lead Independent Director: $30,000

2. Annual Committee Chair Service Retainer:
    a. Chair of the Audit Committee: $16,000
    b. Chair of the Compensation Committee: $12,000
    c. Chair of the Nominating and Corporate Governance Committee: $10,000

3. Annual Committee Member Service Retainer (not applicable to Committee Chairs):
    a. Member of the Audit Committee: $8,000
    b. Member of the Compensation Committee: $6,000
    c. Member of the Nominating and Corporate Governance Committee: $5,000

Equity Compensation

Eligible Directors will receive the equity compensation set forth below for his or her Board service upon and following the Effective Date. The equity compensation set forth below will be granted under the Plan or any successor thereto. All stock options granted under this policy will be nonstatutory stock options, with an exercise price per share equal to 100% of the Fair Market Value (as defined in the Plan) of the Company's common stock ("***Common Stock***") on the date of grant, and a term of ten years from the date of grant (subject to earlier termination as provided in the Plan).

1. Initial Grant: For each Eligible Director who is first elected or appointed to the Board on or following the Effective Date, upon such Eligible Director's initial election or appointment to the Board, or, if such date is not a market trading day, the first market trading day thereafter, the Eligible Director will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted a stock option to purchase 50,000 shares of Common Stock (the "***Initial Grant***"); it being understood that, prior to the grant of the Initial Grant, the Board or the Compensation Committee of the Board may review the value and form of the Initial Grant to ensure that the Initial Grant provides a form and level of compensation that is consistent with then-applicable market practice and, based on such review, the Board or the Compensation Committee may, in its discretion, adjust the number of shares of Common Stock subject to the Initial Grant and/or the form of the Initial Grant, including providing that the Initial Grant be made in the form of stock options and/or a combination of stock options and restricted stock units. The shares subject to each Initial Grant will vest in equal monthly installments over a three-year period such that the option is fully vested on the third anniversary of the date of grant, and will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service (as defined in the Plan) through the applicable vesting date.

Annual Grants: On the date of each annual stockholder meeting of the Company held after the Effective Date, each Eligible Director who continues to serve as a non-employee member of the Board following such stockholder meeting will be automatically, and without further action by the Board or the Compensation Committee of the Board, granted (i) a stock option to purchase 48,050 shares of Common Stock, and (ii) an award of 32,050 restricted stock units (together, the "***Annual Grants***"); it being understood that, prior to the grant of the Annual Grants, the Board or the Compensation Committee of the Board may review the value and form of the Annual Grants to ensure that the Annual Grants provide a form and level of compensation that is consistent with then-applicable market practice and, based on such review, the Board or the Compensation Committee may, in its discretion, adjust the number of shares of Common Stock subject to the Annual Grants and/or the form of the Annual Grants, including the proportion of the Annual Grants comprised of stock options and the proportion comprised of restricted stock units. The shares subject to the

Annual Grants will vest in full on the earlier of the first anniversary of the date of grant or the next annual stockholder meeting, subject to the Eligible Director's Continuous Service (as defined in the Plan) through such vesting date; provided, further, that the Annual Grants will vest in full upon a Change in Control (as defined in the Plan), subject to the Eligible Director's Continuous Service through the date of such Change in Control.

Reimbursement of Expenses

Eligible Directors will be reimbursed by the Company for reasonable and customary expenses incurred in connection with attendance at Board and committee meetings, in accordance with the Company's policies as in effect from time to time.

Non-Employee Director Compensation Limit

As provided in the Plan and notwithstanding the foregoing, the aggregate value of all compensation granted or paid, as applicable, to any individual for service as a Non-Employee Director (as defined in the Plan) with respect to any period commencing on the date of the Company's annual meeting of stockholders for a particular year and ending on the day immediately prior to the date of the Company's annual meeting of stockholders for the next subsequent year (the "***Annual Period***"), including awards granted under the Plan and cash fees paid by the Company to such Non-Employee Director, will not exceed (1) $750,000 in total value or (2) in the event such Non-Employee Director is first appointed or elected to the Board during such Annual Period, $1,000,000 in total value, in each case calculating the value of any equity awards based on the grant date fair value of such equity awards for financial reporting purposes. As provided in the Plan, this limitation will apply commencing with the Annual Period that begins on the Company's first Annual Meeting of Stockholders following the effective date of the Plan.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the following Registration Statements:

(1) Registration Statement (Form S-8 No. 333-286176) pertaining to the Acumen Pharmaceuticals, Inc. 2021 Equity Incentive Plan and the Acumen Pharmaceuticals, Inc. 2021 Employee Stock Purchase Plan,
(2) Registration Statement (Form S-3 No. 333-278280) of Acumen Pharmaceuticals, Inc.,
(3) Registration Statement (Form S-8 No. 333-278267) pertaining to the Acumen Pharmaceuticals, Inc. 2021 Equity Incentive Plan and the Acumen Pharmaceuticals, Inc. 2021 Employee Stock Purchase Plan,
(4) Registration Statement (Form S-8 No. 333-270902) pertaining to the Acumen Pharmaceuticals, Inc. 2021 Equity Incentive Plan and the Acumen Pharmaceuticals, Inc. 2021 Employee Stock Purchase Plan,
(5) Registration Statement (Form S-3 No. 333-266004) of Acumen Pharmaceuticals, Inc.,
(6) Registration Statement (Form S-8 No. 333-263947) pertaining to the Acumen Pharmaceuticals, Inc. 2021 Equity Incentive Plan and the Acumen Pharmaceuticals, Inc. 2021 Employee Stock Purchase Plan, and
(7) Registration Statement (Form S-8 No. 333-257666) pertaining to the Acumen Pharmaceuticals, Inc. 2013 Amended and Restated Stock Performance Plan, the Acumen Pharmaceuticals, Inc. 2021 Equity Incentive Plan, and the Acumen Pharmaceuticals, Inc. 2021 Employee Stock Purchase Plan;

of our report dated March 26, 2026, with respect to the financial statements of Acumen Pharmaceuticals, Inc. included in this Annual Report (Form 10-K) of Acumen Pharmaceuticals, Inc. for the year ended December 31, 2025.

/s/ Ernst & Young LLP

Philadelphia, Pennsylvania
March 26, 2026

Exhibit 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 ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Daniel O'Connell, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Acumen Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2026

By: /s/ Daniel O'Connell

Daniel O'Connell
Chief Executive Officer
(Principal Executive Officer)

Exhibit 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 ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Matthew Zuga, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 of Acumen Pharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 26, 2026

By: /s/ Matthew Zuga

Matthew Zuga
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Accounting Officer)

Exhibit 32.1

CERTIFICATION OF PERIODIC FINANCIAL REPORTS PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Acumen Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Daniel O'Connell, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2026

By: /s/ Daniel O'Connell

Daniel O'Connell
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION OF PERIODIC FINANCIAL REPORTS PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report on Form 10-K of Acumen Pharmaceuticals, Inc. (the "Company") for the year ended December 31, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Matthew Zuga, Chief Financial Officer and Chief Business Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

(1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: March 26, 2026

By: /s/ Matthew Zuga

Matthew Zuga
Chief Financial Officer and Chief Business Officer
(Principal Financial Officer and Accounting Officer)