

Risk Factors Comparison 2025-03-27 to 2024-03-26 Form: 10-K

Legend: New Text ~~Removed Text~~ Unchanged Text Moved Text Section

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 focused on pioneering a novel disease- modifying therapeutic approach to treat 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 very 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 clearance 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 ~~expect to initiate~~ **initiated** our Phase 2 clinical trial, ALTITUDE- AD, in ~~May the first half of 2024~~ **and completed enrollment in March 2025**. We also ~~conducted~~ ~~expect to initiate~~ a Phase 1 clinical trial investigating a subcutaneous dosing option of sabirnetug in mid- 2024 **and announced results in March 2025**. We ~~have previously~~ experienced delays in ~~clinical trial~~ site activation and ~~patient enrollment~~ ~~for with respect to our~~ INTERCEPT- AD ~~clinical trial, and that we believe were principally related to effects of the COVID- 19 pandemic.~~ ~~We cannot assure you that we will not experience additional delays in site activation or enrollment in~~ **our current or 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, ~~2024 and 2023 and 2022~~, our net losses were \$ ~~102. 3 million and \$ 52. 4 million and \$ 42. 9 million~~, respectively. As of December 31, ~~2023~~ **2024**, we had an accumulated deficit of \$ ~~222. 325. 8-1 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 ~~INTERCEPT- AD clinical trial 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. 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. 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. 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 ~~additional~~ 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, ~~2023~~ **2024**, we had \$ ~~66.35~~ **9.6** million in cash and cash equivalents and \$ ~~239.195~~ **2.9** million in marketable securities; included in this amount is the first tranche of \$ 30.0 million that we received under our ~~Loan loan and Security security Agreement agreement~~ with K2 HealthVentures LLC, or the Loan Agreement, which was received on November 10, 2023. 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 the first half of 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, including for 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 ~~and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide~~. 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. 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%. ~~The Federal Reserve has recently raised, and may in the future further raise, interest rates to combat the effects of recent high inflation.~~ 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 ~~INTERCEPT-AD Phase 1~~ **Phase 1 clinical trial trials** of sabirnetug, which is currently our only product candidate. Before seeking marketing approval from regulatory authorities for the sale of sabirnetug, 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 patient enrollment in ~~INTERCEPT-AD, ALTITUDE-AD~~ and other clinical trials of sabirnetug;
- sufficiency of our financial and other resources to complete the necessary clinical trials;
- the results from ~~INTERCEPT-AD, 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 ~~cGMP~~ **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, 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 achieving achieve and maintaining** ~~---~~ **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 ~~or not~~ 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, ~~review or approval~~ compared to conventional FDA procedures, ~~and receiving a Fast Track designation does not provide any assurance of ultimate FDA approval.~~ 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 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 AβOs, to treat AD. Our approach is based on research on AβOs, globular assemblies of the amyloid- beta, or Aβ, peptide that are distinct from other forms of amyloid. AβOs have gained **increasing** scientific acceptance as **important a primary toxins- 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- Aβ / plaque immunotherapies because **of it its is highly selective selectivity** for soluble AβOs. We believe that sabirnetug is the most advanced immunotherapy candidate in development that was designed to selectively target AβOs. 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 ~~conducted~~ **completed** its first clinical trial, ~~had~~ **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, we have had limited interactions with the FDA and have received important feedback on the design of ALTITUDE- AD; **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~~ **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 submission 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 differ~~ **differing views from each other** 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; ~~and~~ 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, including but not limited to, in the United States, as a result of the 2025 change in presidential administration, 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 INTERCEPT-AD, 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 ~~, if any,~~ 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 for example,** 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; ~~we could be sued~~ **personal injury claims, actions, lawsuits and held liable proceedings that may arise from exposure to for or harm caused to patients 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 ~~. We cannot predict how successful we will be at enrolling subjects in future clinical trials.~~ 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, 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 ~~future~~ 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. ~~We have completed the INTERCEPT-AD Phase 1 clinical trial in patients with AD and expect to initiate a Phase 2 clinical trial in the first half of 2024.~~ 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 clearance 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 ~~as well~~. 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. **Due to the recent change in U. S. presidential administration, we face uncertainty regarding potential regulatory developments that may adversely affect our business. We face uncertainty regarding the regulatory environment following the change in U. S. presidential administration in January 2025. While many of the new Trump administration's proposed policies appear to be focused on deregulation, the new administration and federal government could adopt legislation, regulation 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, because one objective of the current Trump administration appears to be to decrease spending in the federal government, the FDA could face staff reductions, which could 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 executive actions that may be taken under the current Trump 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, **including 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 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 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 ~~candidate~~ 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 understood 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, ~~or HHS~~, state attorneys general, members of our 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 A β 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. **Eisai and Biogen Inc., or Biogen, have submitted a BLA to the FDA for a subcutaneous weekly dosing option of Leqembi, with a Prescription Drug User Fee Act date in August 2025.** 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, and expects regulatory action from the FDA on approved donanemab in 2024.** Other companies known to be developing therapies with A β -, A β O-, 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 Inc., ~~Chugai Pharmaceutical Co. Ltd.~~, Cognition Therapeutics, Inc., **Denali Therapeutics, Inc., or Denali**, ~~Eisai Co., Ltd.~~, Eli Lilly and Company, Grifols, S. A., KalGene Pharmaceuticals, Inc., Neurimmune AG, ~~Novartis AG~~, Priavoid GmbH, ProMIS Neurosciences, Inc., Prothena Biosciences, Inc., Roche Holding AG (including Genentech, Inc., its wholly-owned subsidiary) ~~Vaxxinity, Inc. or Roche~~, Vivoryon Therapeutics N. V. 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 Inc., AC Immune SA, Alector Inc., Anavex Life Sciences Corp., Annovis Bio, Inc., Athira Pharma, Inc., Biogen Inc., Biohaven Pharmaceuticals, Inc., Cassava Sciences, Inc., ~~Denali Therapeutics, Inc.~~, Eisai Co., Ltd., Johnson & Johnson (including Janssen Inc. its wholly-owned subsidiary), H. Lundbeck A/S, Lighthouse **Pharma Pharmaceuticals, Inc.**, Roche Holding AG, 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 ~~(4)~~ 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 ~~health~~ **healthcare** ~~care~~ programs (e. g., Medicare, Medicaid, TRICARE), managed care providers, private health insurers, health maintenance organizations, ~~and other organizations~~ **is are** essential for most patients to be able to afford medical services and pharmaceutical products such as our product candidates. ~~One payor' s determination to provide coverage for a drug product does not assure that other payors will also provide coverage.~~ 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. ~~In the United States, there are numerous federal and state privacy and data security laws and regulations governing the collection, use, disclosure and protection of personal information, including federal and state health information privacy laws, federal and state security breach notification laws, and federal and state consumer protection laws.~~ 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 Federal Trade Commission 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.** In addition, states are ~~constantly~~ adopting new laws or amending existing laws, requiring attention to frequently changing regulatory requirements. **Almost 20** ~~For example, California enacted the California Consumer Privacy Act, or CCPA, which took effect on January 1, 2020, became enforceable by the California Attorney General on July 1, 2020, and has been dubbed the first “GDPR-like” law in the United States. The CCPA gives California residents expanded rights to access and delete their-~~ **other** ~~personal information, opt out of certain personal information sharing, receive detailed information about how their personal information is used by requiring covered companies to provide new disclosures to California consumers (as that term is broadly defined) and provide such consumers new ways to opt out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. California has created a data privacy agency authorized to implement and enforce the CCPA, which could result in increased enforcement. Although the CCPA currently exempts certain health-related information, including clinical trial data, the CCPA may increase our compliance costs and potential liability. Other states have~~ **now** ~~considered and / or enacted similar privacy laws, including Virginia, Connecticut, Colorado and Utah, which passed~~ **comprehensive** ~~privacy laws that~~ **went have taken effect or will come** ~~into operation in 2023~~ **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 increases the cost and complexity of operating our business and increases 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 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. ~~Legal requirements in many countries relating to the collection, storage, processing and transfer of personal data continue to evolve.~~ 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 (£ 17. 5 million) or 4 % of the annual global revenues of the noncompliant company, whichever is greater. 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 costs and reduce our net sales. 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 the Phase 1 and 2** 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 intend to engage CROs and other third parties to conduct our planned nonclinical studies or clinical trials, including ~~INTERCEPT-AD,~~ ALTITUDE- AD and future clinical trials of sabirnetug, 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 ~~GCPs-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 ~~GCPs-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 ~~GCP-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 war in Ukraine 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 our product candidate, and 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 non-disclosure and confidentiality agreements 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, or PTE, 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, or SPC. 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 licenses 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 ~~AB amyloid beta~~- 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 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. 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, **their** 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 ~~of~~ 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~~ **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, **including 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 or 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;
- ~~federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers~~;
- 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, **it is governmental authorities may possible possibly conclude** that **some of our business practices are non- compliant** activities could be subject to challenge under one or more of such laws. 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 **significant** penalties, including, without limitation, civil ; **and** criminal **and administrative** penalties, damages, fines , **disgorgement**, 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 **harm 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 **Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, 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, in which manufacturers must agree to offer point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D. More generally, the ACA expanded health care coverage through Medicaid expansion and the implementation of the "individual mandate" for health insurance coverage. Beyond the ACA, there have been ongoing health care reform efforts. Drug pricing and payment reform was a focus of the Trump Administration and has been a focus of the Biden Administration. For example, federal legislation enacted in 2021 eliminated the statutory cap on Medicaid drug rebate Rebate program rebates (currently set at 100% of a drug's "average manufacturer price") effective January 1, 2024. As another 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, which have varying implementation dates, 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 ACA Medicare Part D coverage gap discount program) and a drug price negotiation program for certain high spend Medicare Part B and D drugs. The IRA is anticipated to have a significant impact on the pharmaceutical industry. The focus on health care reform, including reform of drug pricing and payment, has continued in the wake of the IRA. For example, in 2022, subsequent to the enactment of the IRA, the Biden administration released announced its commitment to expanding certain IRA reforms. There have been significant and wide-ranging reforms to federal policy and the federal government under the new Trump administration, and we face substantial uncertainty as to how current or any future reforms initiated by the administration may impact our business and operations. For example, drug pricing and payment reform was a focus of the prior Trump administration and that focus is likely to continue under the new Trump administration. Other potential healthcare reform efforts under the Trump administration may affect access to healthcare coverage or the funding of healthcare benefits. There is significant uncertainty regarding the nature or impact of any such reform implemented by the Trump administration through executive action order directing the HHS to report on how the Center for Medicare and Medicaid Innovation, or CMMI, could be leveraged to test new models for lowering drug costs for Medicare and Medicaid beneficiaries, which report proposed various models that CMMI is currently developing. Healthcare reform efforts have been and may continue to be subject to scrutiny and legal challenge. For example, with respect to the ACA, tax reform legislation was enacted that eliminated the tax penalty established for individuals who do not maintain mandated health insurance coverage beginning in 2019 and, in 2021, the U. S. Supreme Court dismissed the latest judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. As another example, revisions to regulations under the federal anti-kickback statute would remove protection for traditional Medicare Part D discounts offered by pharmaceutical manufacturers to pharmacy benefit managers and health plans. Pursuant to court order, the removal was delayed and subsequent legislation imposed a moratorium on implementation of the rule until January 2032. As another example, the IRA drug price negotiation program has been challenged in litigation filed by various pharmaceutical manufacturers and industry groups. Moreover, there has recently been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries, proposed and enacted legislation and executive orders issued by the prior presidential administration designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. 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. General legislative cost control measures may also affect reimbursement for our product candidates. The Budget Control Act, 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 ~~health~~ ~~healthcare~~ ~~care~~ 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, ~~and which~~ could materially harm our business and our financial results. In addition, delays in receipt of or failure to receive regulatory clearances 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~~ ~~U. K.~~ 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 ~~health~~ ~~healthcare~~ ~~care~~ 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 ~~health~~ ~~healthcare~~ ~~care~~ 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 ~~over the Internet~~, security incidents, disruptions, ~~attachments to emails~~, persons inside our organization, or persons with access to systems inside our organization. The risk of a security breach or disruption, particularly through 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 ~~was~~ **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, and 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 accounts payable, 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 ~~The Nasdaq Global Select Market~~, 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. An 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 24~~, ~~2024~~ **2025**, our stock price fluctuated from a low of \$ 1. ~~87~~ **10** 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 ~~INTERCEPT-AD~~, 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, 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. As of March 20, 2024, 2024-2025, we had 60,079,573, 778,425 shares of common stock outstanding. All of the shares of common stock sold during the initial public offering are currently freely tradable, except for any shares held by our affiliates as defined in Rule 144 under the Securities Act of 1933, or the Securities Act. Additionally, the holders of approximately 18.6 million shares of common stock, or their transferees, have rights, subject to some conditions, with respect to registration of such shares under the Securities Act pursuant to an investor rights agreement between such holders and us. If such holders, by exercising their registration rights, sell a large number of shares, they could adversely affect the market price for our common stock. If we file a registration statement for the purpose of selling additional shares to raise capital, we may be required to offer these holders the right to participate in the offering and, if we are required to include shares held by these holders pursuant to the exercise of their registration rights, our ability to raise capital may be impaired. We have filed registration statements on Form S-8 under the Securities Act registering 15, approximately 12, 334,817, 367,735 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, including the net proceeds from our initial public offering, 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, including the net proceeds from our initial public offering. 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, 2023-2024, we had federal and state NOL carryforwards of \$ 67-91. 2-0 million and \$ 46-28. 9-6 million, respectively. Of the total federal NOLs of \$ 67-91. 2-0 million, \$ 6. 5 million will begin expiring in the year 2028 as will the state NOLs if not utilized. The remaining \$ 60-84. 7-5 million of federal NOL carryforwards as of December 31, 2023-2024 do not expire due to the enactment of the Tax Cuts and Jobs Act in of 2017, or the Tax Act, although are limited to eighty percent-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 "5-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 recent-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 Commission-SEC and other government agencies caused by funding shortages, staff and workforce reductions or global health concerns could hinder their-- 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 most recently from December 22, 2018 to January 25, 2019, 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, 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, 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 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.