Risk Factors Comparison 2025-03-28 to 2024-03-26 Form: 10-K

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You should carefully consider the following risk factors, together with the other information contained in this Annual Report, including our **consolidated** financial statements and the related notes and " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before making an investment decision regarding our securities. We cannot assure you that any of the events discussed in the risk factors below will not occur. These risks could have a material and adverse impact on our business, results of operations, financial condition and growth prospects. If that were to happen, the trading price of our common stock could decline. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations or financial condition. In this section, we first provide a summary of the principal risks and uncertainties we face and then provide a full set of risk factors and discuss them in greater detail. **Risk Factors** Summary ~~of~~ Risks Related to **the Development and Regulatory Approval of** Our **Product Candidates • We currently depend entirely on the success of cretostimogene, which is our only product candidate. If we are unable to advance cretostimogene in clinical development, obtain regulatory approval and ultimately commercialize cretostimogene, or experience significant delays in doing so, our** ~~Business~~ **business • We currently depend entirely on the success of cretostimogene,which is our only product candidate.If we are unable to advance cretostimogene in clinical development,obtain regulatory approval and ultimately commercialize cretostimogene,or experience significant delays in doing so,our business** will be materially harmed.• Cretostimogene is based on a novel approach to the treatment of cancer,which makes it difficult to predict the time and cost of product candidate development and subsequently obtaining regulatory approval,if at all.• Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes,and ~~the~~ results of **prior** preclinical studies and early clinical trials are not necessarily predictive of future results.Cretostimogene or any future product candidates may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis,if at all.• Use of cretostimogene or any future product candidates could be associated with adverse side effects,adverse events or other properties or safety risks ~~,which could delay or preclude regulatory approval,cause us to suspend or discontinue clinical trials,abandon cretostimogene or any future product candidate,limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business~~ • We have a relatively limited operating history, have incurred significant operating losses since our inception, and expect to incur significant losses for the foreseeable future. We may never generate any revenue or become profitable or, if we achieve profitability, we may not be able to sustain it. • We will require substantial additional capital to finance our operations, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our development programs, commercialization efforts or other operations. • We currently depend entirely on the..... events or other properties or safety risks **Risks Related** ~~, which could delay or preclude regulatory approval, cause us~~ to **Our Intellectual Property** ~~suspend or discontinue clinical trials, abandon cretostimogene or any future product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects. • We face significant competition, and if our competitors develop and commercialize technologies or product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than cretostimogene or any future product candidates we develop, our business and our ability to develop and successfully commercialize products will be adversely affected. • We rely on third parties to conduct our clinical trials and preclinical studies, and these third parties may not perform satisfactorily, which could delay, prevent, or impair our development or commercialization efforts. • We rely on third parties for the manufacture and shipping of cretostimogene for clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of cretostimogene or future product candidates or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts.~~ • If we are unable to obtain, maintain, and enforce patent or other intellectual property protection for cretostimogene or any future product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize cretostimogene or any future product candidates, may be adversely affected. Risks Related to Our Limited Operating History..... and Regulatory Approval of Our Product Candidates We currently only have one product candidate, cretostimogene, which is in Phase 3 clinical development. Our business presently depends entirely on our ability to successfully develop, obtain regulatory approval for, and commercialize cretostimogene in a timely manner. This may make an investment in our company riskier than similar companies that have multiple product candidates in active development and may be able to better sustain the delay or failure of a lead product candidate. The success of cretostimogene will depend on several factors, including the following: • successful initiation and enrollment of clinical trials and completion of clinical trials with favorable results **, including the full data readouts from the ongoing Phase 3 clinical trials for cretostimogene** ; • acceptance of regulatory submissions by the U. S. ~~Food and Drug Administration (~~ FDA ~~)~~ or comparable foreign regulatory authorities for the conduct of clinical trials of cretostimogene and of our proposed designs of planned clinical trials of cretostimogene; • the frequency and severity of adverse events observed in clinical trials and preclinical studies; • maintaining and establishing relationships with contract research organizations (CROs) and clinical sites for the clinical development of cretostimogene, and ability of such CROs and clinical sites to comply with clinical trial protocols, ~~Good Clinical Practices (~~ GCPs ~~)~~ and other applicable requirements; • demonstrating the safety, purity and potency (or efficacy) of cretostimogene to the satisfaction of applicable regulatory authorities, including

by establishing a safety database of a size satisfactory to regulatory authorities; • receipt and maintenance of regulatory approvals from applicable regulatory authorities, including approvals of ~~Biologics License Applications (~~BLAs ~~)~~ from the FDA; • maintaining relationships with our third- party manufacturers and their ability to comply with current Good Manufacturing Practices (cGMPs) as well as timely making arrangements with our third- party manufacturers for, or establishing our own, commercial manufacturing capabilities at a cost and scale sufficient to support commercialization; • establishing sales, marketing and distribution capabilities and launching commercial sales of cretostimogene, if and when approved, whether alone or in collaboration with others; • obtaining, maintaining, protecting and enforcing patent and any potential trade secret protection or regulatory exclusivity for cretostimogene; • maintaining an acceptable safety profile of cretostimogene following regulatory approval, if any; • maintaining and growing an organization of people who can develop and, if approved, commercialize, market and sell cretostimogene; and • acceptance of our products, if approved, by patients, the medical community and third- party payors. If we are unable to develop, obtain regulatory approval for, or if approved, successfully manufacture and commercialize cretostimogene, or if we experience delays as a result of any of the above factors or otherwise, our business would be materially harmed. We have concentrated our research and development efforts on cretostimogene, and our future success largely depends on the successful development of the oncolytic approach underlying this product candidate. In particular, cretostimogene is an engineered adenovirus designed to replicate and eliminate cancer cells while also stimulating an anti- tumor immune response. To our knowledge, there are no FDA- approved products for the treatment of cancer that utilize a replication- competent adenovirus. We expect the novel nature of cretostimogene to create further challenges in obtaining regulatory approval. Few viral immunotherapies have been approved globally or by the FDA to date. While the first oncolytic viral immunotherapy, talimogene laherparepvec (Imlygic, Amgen), has received FDA approval, regulatory agencies have reviewed relatively few viral immunotherapy product candidates such as cretostimogene. This may lengthen the regulatory review process, increase our development costs and delay or prevent commercialization of our product candidates. Further, any viral immunotherapies that are approved may be subject to extensive post- approval regulatory requirements, including requirements pertaining to manufacturing, distribution and promotion. We may need to devote significant time and resources to compliance with these requirements. In addition, cretostimogene is a live, gene- modified virus for which the FDA and other comparable foreign regulatory authorities and other public health authorities, such as the Centers of Disease Control and Prevention and hospitals involved in clinical studies, have established additional safety and contagion rules and procedures, which could establish additional hurdles for the development, manufacture or use of our vectors. These hurdles may lead to delays in the conduct of clinical trials or in obtaining regulatory approvals for further development, manufacturing or commercialization of our product candidates. We may also experience delays in transferring our process to commercial partners, which may prevent us from completing our clinical trials or commercializing our product candidates on a timely or profitable basis, if at all. ~~Clinical and preclinical drug development involves a lengthy and expensive process with uncertain timelines and outcomes, and the results of preclinical studies and early clinical trials are not necessarily predictive of future results. Cretostimogene or any future product candidates may not achieve favorable results in clinical trials or preclinical studies or receive regulatory approval on a timely basis, if at all.~~ Drug development is expensive and can take many years to complete, and its outcome is inherently uncertain. We cannot guarantee that any clinical trials or preclinical studies will be conducted as planned, including whether we are able to meet expected timeframes for data readouts, or completed on schedule, if at all, and failure can occur at any time during the trial or study process, including due to factors that are beyond our control. Despite promising preclinical or clinical results, cretostimogene or any other future product candidate can unexpectedly fail at any stage of clinical or preclinical development. The historical failure rate for product candidates in our industry is high. The results from preclinical studies or clinical trials of cretostimogene, any future product candidate, or a competitor' s product candidate in the same class may not predict the results of later clinical trials of cretostimogene or any future product candidate, and interim, topline or preliminary results of a clinical trial are not necessarily indicative of final results. Cretostimogene or any future product candidate in later stages of clinical trials may fail to show the desired characteristics despite having progressed through preclinical studies and initial clinical trials. It is not uncommon to observe results in clinical trials that are unexpected based on preclinical studies and early clinical trials, and many product candidates fail in clinical trials despite very promising early results. **We 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 interim, topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated. Topline and preliminary data also remain subject to audit and verification procedures that may result, in the final data being materially different from the topline or preliminary data we have previously published. As a result, topline and preliminary data should be viewed with caution until the final data are available.** Moreover, ~~preclinical and~~ **the information we choose to publicly disclose regarding a particular study or** clinical ~~data may be susceptible to varying interpretations~~ **trial is based on what is typically extensive information,** and ~~analyses~~ **you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business** . A number of companies in the biopharmaceutical and biotechnology industries have suffered significant setbacks in clinical development even after achieving promising results in earlier studies. Such setbacks have occurred and may occur for many reasons, including, but not limited to: clinical sites and investigators may deviate from clinical trial protocols, whether due to lack of training or otherwise, and we may fail to detect any such deviations in a timely manner; patients may fail to adhere to any required clinical trial procedures, including any requirements for post- treatment follow- up; our product candidates may fail to demonstrate safety, purity or potency (or efficacy) in certain patient subpopulations, which has not been observed in earlier trials due to limited sample size, lack of analysis or otherwise; or our clinical trials may not adequately represent the patient

populations we intend to treat, whether due to limitations in our trial designs or otherwise, such as where one patient subgroup is overrepresented in the clinical trial. There can be no assurance that we will not suffer similar setbacks despite the data we observed in earlier or ongoing studies. **Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects.** Based upon negative or inconclusive results, we or any current or any future collaborator may decide, or regulators may require us, to conduct additional preclinical studies or clinical trials, which would cause us to incur additional operating expenses and delays and may not be sufficient to support regulatory approval on a timely basis or at all **. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock** . As a result, we cannot be certain that our ongoing and planned clinical trials or preclinical studies will be successful. Any safety concerns observed in any one of our clinical trials in our targeted indications could limit the prospects for regulatory approval of cretostimogene in those and other indications, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Any difficulties or delays in the commencement or completion, or the termination or suspension, of our current or planned clinical trials or preclinical studies could result in increased costs to us, delay or limit our ability to generate revenue or adversely affect our commercial prospects. Before obtaining approval from regulatory authorities for the sale of cretostimogene or any future product candidates, we must conduct extensive clinical trials to demonstrate the safety, purity and potency (or efficacy) of the product candidates in humans. In addition, before we can initiate clinical development for any future preclinical product candidates, we must submit the results of preclinical studies to the FDA or comparable foreign regulatory authorities along with other information, including information about product candidate CMC and our proposed clinical trial protocol, as part of an Investigational New Drug application (IND) or similar regulatory submission, and we are also required to submit comparable applications to foreign regulatory authorities for clinical trials outside of the United States. The FDA or comparable foreign regulatory authorities may require us to conduct additional preclinical studies for any future product candidates before it allows us to initiate clinical trials under any IND or similar regulatory submission, which may lead to delays or increase the costs of developing future product candidates. Moreover, issues may arise that could cause regulatory authorities to suspend or terminate our ongoing or planned clinical trials. Any such delays in the commencement or completion, or the termination or suspension, of our ongoing and planned clinical trials or preclinical studies could significantly affect our product development timelines and product development costs. We do not know whether our planned clinical trials or preclinical studies will begin on time or if our ongoing or future trials or studies will be completed on schedule, if at all. The commencement, data readouts and completion of clinical trials and preclinical studies can be delayed for a number of reasons, including delays related to: • inability to obtain animals or materials to initiate and generate sufficient preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical trials; • obtaining allowance from regulatory authorities to commence a trial or reaching a consensus with regulatory authorities on trial design; • the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials; • any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; • delays in identifying, recruiting, and training suitable clinical investigators; • obtaining approval from one or more ~~institutional review boards (~~ IRBs ~~)~~ or ~~ethics committees (~~ ECs ~~)~~ at clinical trial sites; • IRBs / ECs refusing to approve, suspending, or terminating the trial at an investigational site, precluding enrollment of additional patients, or withdrawing their approval of the trial; • changes to the clinical trial protocol; • clinical sites deviating from the trial protocol or dropping out of a trial; • failure by our CROs to perform in accordance with GCP requirements or applicable regulatory requirements or guidelines in other countries; • obtaining sufficient quantities of cretostimogene or any future product candidates and related raw materials and ~~n- Dodecyl- ß- D- maltoside (~~ DDM ~~)~~ or obtaining sufficient quantities of combination therapies or other materials needed for use in clinical trials and preclinical studies; • patients failing to enroll or remain in our trials at the rate we expect, or failing to return for post- treatment follow- up, including patients failing to remain in our trials due to movement restrictions, health reasons or otherwise resulting from any future public health concerns; • patients choosing alternative treatments for the indications for which we are developing cretostimogene or any future product candidates, or participating in competing clinical trials; • lack of adequate funding to continue the clinical trials or preclinical studies or costs being greater than we anticipate; • patients experiencing severe or serious unexpected drug- related adverse effects; • occurrence of serious adverse events in trials of the same class of agents conducted by other companies that could be considered similar to cretostimogene or any future product candidates; • selection of clinical endpoints that require prolonged periods of clinical observation or extended analysis of the resulting data; • transfer of manufacturing processes to larger- scale facilities operated by third- party manufacturers, delays or failure by our third- party manufacturers or us to make any necessary changes to such manufacturing process, or failure of such third- party manufacturers to produce clinical trial materials in accordance with cGMP regulations or other applicable requirements; and • third parties being unwilling or unable to satisfy their contractual obligations to us in a timely manner. Clinical trials must be conducted in accordance with the FDA and other applicable regulatory authorities' legal requirements, regulations or guidelines, and are subject to oversight by these governmental agencies and ECs or IRBs at the medical institutions where the clinical trials are conducted. We could also encounter delays if a clinical trial is suspended or terminated by us, by the IRBs of the institutions in which such trials are being conducted, by a data safety monitoring board for such trial or by the FDA or comparable foreign regulatory authorities. Such authorities may impose such a suspension, including a clinical hold, or termination due to a number of factors, including, among other reasons, failure to conduct the clinical trial in accordance with GCP and other regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, failure to demonstrate a benefit from using a drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. In addition, changes in regulatory requirements and policies may occur, and we may need to amend clinical trial protocols to comply with these changes. Amendments may require us to resubmit our clinical trial

protocols to IRBs for reexamination, which may impact the costs, timing or successful completion of a clinical trial. Further, we and our collaborators are currently conducting, and we, our collaborators and any future collaborators may in the future conduct, clinical trials in foreign countries, which presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocols as a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, and political and economic risks, including war, relevant to such foreign countries. Moreover, principal investigators for our clinical trials have served and may in the future serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA or comparable foreign regulatory authorities. The FDA or comparable foreign regulatory authority may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA or comparable foreign regulatory authority may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA or comparable foreign regulatory authority, as the case may be, and may ultimately lead to the denial of regulatory approval of cretostimogene or any future product candidates. In addition, we may make formulation or manufacturing changes to cretostimogene or any future product candidate, in which case we may need to conduct additional preclinical studies or clinical trials to bridge our current version of cretostimogene or future product candidate to earlier versions. If we are unable to conduct such studies or trials, or if we otherwise fail to adequately bridge the current versions of our product candidates to earlier versions, then we may be unable to utilize any data we have gathered from studies or trials that evaluated such earlier versions in our planned regulatory submissions, which could delay our programs. For example, in our ongoing studies of cretostimogene we are utilizing materials produced by a different third- party manufacturer than the third- party manufacturer that produced cretostimogene during the initial clinical trials for cretostimogene, and we are unable to demonstrate full comparability between lots produced previously and those produced by our current manufacturer. As a result, we may be required to gather additional data utilizing material produced by our current third- party manufacturer before we are able to submit a BLA for cretostimogene, if ever. Many of the factors that cause, or lead to, the termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize cretostimogene or our future product candidates. In such cases, our competitors may be able to bring products to market before we do, and the commercial viability of cretostimogene or our future product candidates could be significantly reduced. Any of these occurrences may **harm our business, financial condition, results of operations and prospects. Cretostimogene, as both a monotherapy and in combination with other therapies, has shown a potential best- in- class target product profile. Topline data from the Phase 3 BOND- 003 Cohort C trial that was presented as a late- breaking abstract at the 2024 SUO Annual Meeting showed that cretostimogene, as a single agent, achieved a 74. 5 % complete response (CR) at any time in high- risk BCG- unresponsive NMIBC, which was updated at the 2025 Annual EAU Congress to 75. 5 %. As of the data cutoff of September 30, 2024, by Kaplan- Meier estimate, 63. 5 % and 56. 6 % of patients remained in response at 12 months or greater and at 24 months or greater, respectively, while the median DoR was not reached but exceeds 27 months. There were no Grade 3 or greater treatment- related adverse events (TRAEs) or deaths reported. The most common TRAEs (≥ 10 %) were bladder spasm, pollakiuria, micturition urgency, dysuria, and hematuria. No treatment-related discontinuation of cretostimogene was observed, and 97. 3 % of patients completed all expected treatments, demonstrating favorable patient adherence and compliance. While we believe these data from our Phase 3 BOND- 003 trial will support our BLA submission for cretostimogene, the FDA may determine that our Phase 3 BOND- 003 data is insufficient to accept for filing such BLA or for BLA approval and may impose requirements for BLA resubmission, and even if filed by the FDA they may impose requirements to conduct additional clinical trials, or other significant and time-consuming requirements related to clinical data, nonclinical studies or manufacturing, or may issue a complete response letter (CRL). A CRL indicates that the review cycle for the application is complete, and the application will not be approved in its present form. A CRL usually describes the specific deficiencies in the BLA identified by the FDA and may include requirements to conduct additional clinical trials, or other significant and time- consuming requirements related to clinical data, nonclinical studies or manufacturing. If a CRL is issued, the sponsor must resubmit the BLA, addressing all of the deficiencies identified in the letter, or withdraw the application. Even if such data and information are submitted, the FDA may decide that the BLA does not satisfy the criteria for approval, which would** harm our business, financial condition, results of operations and prospects. We may find it difficult to enroll patients in our clinical trials. If we encounter difficulties or delays enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected. Successful and timely completion of clinical trials will require that we identify and enroll a specified number of patients for each of our clinical trials. We may not be able to initiate or continue certain clinical trials for cretostimogene or any future product candidates if we are unable to identify and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA or similar regulatory authorities outside the United States. Patient enrollment, a significant factor in the timing of clinical trials, is affected by many factors, including the size and characteristics of the patient population, the proximity of patients to clinical sites, the eligibility and exclusion criteria for the trial, the design of the clinical trial, the risk that enrolled patients will not complete a clinical trial, our ability to recruit clinical trial investigators with the appropriate competencies and experience, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages and risks of the product candidates being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating as well as any product candidates under development. We will be required to identify and enroll a sufficient number of patients for each of our clinical trials and monitor such patients

adequately during and after treatment. Potential patients for any planned clinical trials may not be adequately diagnosed or identified with the diseases which we are targeting, which could adversely impact the outcomes of our trials and could have safety concerns for the potential patients. Potential patients for any planned clinical trials may also not meet the entry criteria for such trials. Additionally, other pharmaceutical companies targeting bladder cancer are recruiting clinical trial patients from these patient populations, which may make it more difficult to fully enroll our clinical trials. The timing of our clinical trials depends, in part, on the speed at which we can recruit patients to participate in our trials, as well as completion of required follow- up periods. The eligibility criteria of our clinical trials, once established, may further limit the pool of available trial participants. If patients are unwilling or unable to participate in our trials for any reason, including the existence of concurrent clinical trials for similar target populations, the availability of approved therapies, or the fact that enrolling in our trials may prevent patients from taking a different product, or we otherwise have difficulty enrolling a sufficient number of patients, the timeline for recruiting patients, conducting trials and obtaining regulatory approval of cretostimogene or any future product candidates may be delayed. Our inability to enroll a sufficient number of patients for any of our future clinical trials would result in significant delays or may require us to abandon one or more clinical trials altogether. In addition, we rely on, and will continue to rely on, CROs and clinical trial sites to ensure proper and timely conduct of our clinical trials and preclinical studies. Though we have entered into agreements governing their services, we have limited influence over their actual performance. We cannot be certain that our assumptions used in determining expected clinical trial timelines are correct or that we will not experience delays or difficulties in enrollment, or be required by the FDA or other regulatory authority to increase our enrollment, which would result in the delay of completion of such trials beyond our expected timelines. Use of cretostimogene or any future product candidates could be associated with side effects, adverse events or other properties or safety risks, which could delay or preclude regulatory approval, cause us to suspend or discontinue clinical trials, abandon cretostimogene or any future product candidate, limit the commercial profile of an approved label or result in other significant negative consequences that could severely harm our business, financial condition, results of operations and prospects. As is the case with oncology drugs generally, it is likely that there may be side effects and adverse events associated with use of cretostimogene or any future product candidates' use. Results of our, our collaborators' or any future collaborators' clinical trials could reveal a high and unacceptable severity and prevalence of expected or unexpected side effects or unexpected characteristics. Undesirable side effects caused by our product candidates when used alone or in combination with approved or investigational drugs could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label, or lead to the delay or denial of regulatory approval by the FDA or comparable foreign regulatory authorities. The drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition, results of operations and prospects significantly. Moreover, if cretostimogene or any future product candidates are associated with undesirable side effects in clinical trials or demonstrate characteristics that are unexpected, we may elect to abandon their development or 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. Unacceptable enhancement of certain toxicities may be seen when cretostimogene or any future product candidates are combined with standard of care therapies, or when they are used as single agents. We may also be required to modify our development and clinical trial plans based on findings in our ongoing clinical trials. Many compounds that initially showed promise in early- stage testing for treating cancer have later been found to cause side effects that prevented further development of the compounds. It is possible that as we, our collaborators or any future collaborators test cretostimogene or any future product candidates in larger, longer and more extensive clinical trials, including with different dosing regimens, or as the use of these product candidates becomes more widespread following any regulatory approval, more illnesses, injuries, discomforts and other adverse events than were observed in earlier trials, as well as new conditions that did not occur or went undetected in previous trials, may be discovered. If such side effects become known later in development or upon approval, if any, such findings may harm our business, financial condition, results of operations and prospects significantly. In addition, we are studying cretostimogene in combination with other therapies and may do so for future product candidates, which may exacerbate adverse events associated with such product candidate. Patients treated with cretostimogene or future product candidates may also be undergoing surgical, radiation and chemotherapy treatments, which can cause side effects or adverse events that are unrelated to our product candidate but may still impact the success of our clinical trials. The inclusion of critically ill patients in our, our collaborators' or any future collaborators' clinical trials may result in deaths or other adverse medical events due to other therapies or medications that such patients may be using or due to the ~~gravity~~ **severity** of such patients' illnesses. For example, we expect that some of the patients enrolled in our, our collaborators' or any future collaborators' clinical trials will die or experience major clinical events either during the course of such clinical trials or after participating in such trials. In addition, if cretostimogene or any future product candidate receives regulatory approval, and we or others later identify undesirable side effects caused by such product, a number of potentially significant negative consequences could result, including: • regulatory authorities may withdraw, suspend or limit approvals of such product, or seek an injunction against its manufacture or distribution; • we may be required to recall a product or change the way such product is administered to patients; • regulatory authorities may require additional warnings on the label, such as a " black box " warning or a contraindication; • we may be required to implement a Risk Evaluation and Mitigation Strategy (REMS) or create a medication guide outlining the risks of such side effects for distribution to patients; • we may be required to change the way a product is distributed or administered, conduct additional clinical trials or change the labeling of a product or be required to conduct additional post- marketing studies or surveillance; • we could be sued and held liable for harm caused to patients; • sales of the product may decrease significantly or the product could become less competitive; and • our reputation may suffer. Any of these events could prevent us from achieving or maintaining market acceptance and / or physician adoption of the particular product

candidate, if approved, and could significantly harm our business, financial condition, results of operations and prospects. Although we have completed a Phase 2 clinical trial for cretostimogene **and have reported topline data from the Phase 3 BOND- 003 Cohort C trial for cretostimogene** , we have not as an organization completed **the** ~~later- stage or~~ pivotal clinical trials **for cretostimogene** or submitted a BLA, and we may be unable to do so for cretostimogene or any future product candidates. We will need to successfully complete later- stage and pivotal clinical trials in order to obtain FDA or comparable foreign regulatory approval to market cretostimogene or any future product candidates. Carrying out later- stage clinical trials and the submission of a successful BLA or other comparable foreign regulatory submission is a complicated process. As an organization, we have completed ~~one~~ **two** Phase 2 clinical ~~trial~~ **trials** of cretostimogene, and are conducting and plan to conduct additional Phase 3 clinical trials for cretostimogene. We also plan to conduct a number of additional clinical trials of cretostimogene in parallel over the next several years, which may be a difficult process to manage with our limited resources and which may divert attention of management. We have not yet completed any later- stage or pivotal clinical trials for cretostimogene or any other product candidate. We also have limited experience as a company in preparing and submitting marketing applications and have not previously submitted a BLA or other comparable foreign regulatory submission for any product candidate. In addition, **while** we have had ~~limited~~ interactions with the FDA ~~and~~ **regarding our planned BLA submission for cretostimogene, we** cannot be certain ~~how many~~ **that our Phase 3 BOND- 003 Cohort C trial for cretostimogene will be sufficient to support a BLA submission, even if we believe the results are sufficiently positive, or whether** additional clinical trials of cretostimogene or any future product candidate will be required or how such additional trials should 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 and regulatory approval of any of our product candidates. We may require more time and incur greater costs than our competitors and may not succeed in obtaining regulatory approvals of product candidates that we develop. Failure to commence or complete, or delays in, our ongoing or planned clinical trials could prevent us from or delay us in submitting BLAs or other comparable foreign regulatory submissions for and commercializing our product candidates. We intend to develop cretostimogene and future product candidates in combination with other therapies, which exposes us to additional risks. We intend to develop cretostimogene and any future product candidates for use in combination with one or more currently approved cancer therapies. Even if cretostimogene or any future product candidate we develop was to receive regulatory approval or be commercialized for use in combination with other existing therapies, we would continue to bear the risks that the FDA or similar foreign regulatory authorities could revoke approval of the therapy used in combination with cretostimogene or a future product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. The known side effect profile of approved drugs, such as the checkpoint inhibitors we use in combination with cretostimogene, may otherwise negatively affect the results of our trials and could limit the number of patients and physicians who choose to adopt cretostimogene, if approved for use as combination therapy with such drugs. Combination therapies are commonly used for the treatment of cancer, and we would be subject to similar risks if we develop cretostimogene or any future product candidate for use in combination with other drugs or biologics. Developing combination therapies using approved therapeutics, as we plan to do for cretostimogene and our future product candidates, also exposes us to additional clinical risks, such as the requirement that we demonstrate the safety, purity and potency (or efficacy) of each active component of any combination regimen we may develop. If the FDA or similar foreign regulatory authorities revoke the approval of combination agents, or if safety, efficacy, manufacturing, or supply issues arise with the drugs we choose to evaluate in combination with cretostimogene or any future product candidate, we may be unable to obtain approval of or market cretostimogene or any future product candidate for combination therapy regimens. Additionally, if the third- party providers of therapies or therapies in development used in combination with cretostimogene or any future product candidate are unable to produce sufficient quantities for clinical trials or for commercialization of cretostimogene or any future product candidate, or if the cost of combination therapies are prohibitive, our development and commercialization efforts would be impaired, which would have an adverse effect on our business, financial condition, results of operations and prospects. Negative developments in the field of immuno- oncology and, in particular, viral immunotherapy, could damage public perception of any cretostimogene or any future oncolytic product candidates and negatively affect our business. The commercial success of cretostimogene and any future adenovirus- based product candidates will depend in part on public acceptance of the use of immuno- oncology, and, in particular, viral immunotherapy. Adverse events in clinical trials of cretostimogene or any other adenovirus- based product candidates which we may develop, or in clinical trials of other biopharmaceutical companies developing similar products and the resulting publicity, as well as any other negative developments in the field of immuno- oncology that may occur in the future, including in connection with competitor therapies, could result in a decrease in demand for cretostimogene or any other adenovirus- based product candidates that we may develop. These events could also result in the suspension, discontinuation or clinical hold of or modification to our clinical trials. If public perception is influenced by claims that the use of viral immunotherapies is unsafe, whether related to our therapies or those of our competitors, our product candidates may not be accepted by the general public or the medical community and potential clinical trial subjects may be discouraged from enrolling in our, our collaborators' or any future collaborators' clinical trials. In addition, responses by national or state governments to negative public perception may result in new legislation or regulations that could limit our ability to develop or commercialize any product candidates, obtain or maintain regulatory approval or otherwise achieve profitability. More restrictive statutory regimes, government regulations or negative public opinion would have an adverse effect on our business, financial condition, results of operations and prospects and may delay or impair the development and commercialization of our product candidates or demand for any products we may develop. As a result, we may not be able to continue or may be delayed in conducting our development programs. Adverse developments in clinical trials of other immunotherapy products based on viruses, like oncolytic viruses, may result in a disproportionately negative effect for cretostimogene or any future product candidates as compared to other products in the field of infectious disease and immuno- oncology that are not based on viruses. Future

negative developments in the biopharmaceutical industry could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of cretostimogene or any future product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our product candidates. We may not be successful in our efforts to investigate cretostimogene in additional indications. We may expend our limited resources to pursue a new product candidate or a particular indication for cretostimogene and fail to capitalize on product candidates or indications that may be more profitable or for which there is a greater likelihood of success. Because we have limited financial and managerial resources, we focus on the development of cretostimogene for specific indications. We may fail to generate additional clinical development opportunities for cretostimogene for a number of reasons, including that cretostimogene may, in indications we are seeking or may seek in the future, be shown to have harmful side effects, limited to no efficacy or other characteristics that suggest it is unlikely to receive marketing approval and / or achieve market acceptance in such potential indications. Our resource allocation and other decisions may cause us to fail to identify and capitalize on viable potential product candidates or additional indications for cretostimogene. Our spending on current and future research and development programs for new product candidates or additional indications for cretostimogene may not yield any commercially viable product candidates or indications. If we do not accurately evaluate the commercial potential or target market for a particular indication or product candidate, we may fail to develop such product candidate or indication, or relinquish valuable rights to that product candidate through collaborations, license agreements and other similar arrangements in cases where it would have been more advantageous for us to retain sole development and commercialization rights to such indication or product candidate, or negotiate less advantageous terms for any such arrangements than is optimal. Additionally, we may pursue additional in- licenses or acquisitions of development- stage assets or programs, which entails additional risk to us. Identifying, selecting and acquiring promising product candidates requires substantial technical, financial and human resources expertise. Efforts to do so may not result in the actual acquisition or license of a particular product candidate, potentially resulting in a diversion of our management' s time and the expenditure of our resources with no resulting benefit. For example, if we are unable to identify programs that ultimately result in approved products, we may spend material amounts of our capital and other resources evaluating, acquiring and developing products that ultimately do not provide a return on our investment. We are currently conducting and may in the future conduct certain of our clinical trials for cretostimogene or any future product candidate outside of the United States. However, the FDA and other foreign equivalents may not accept data from such trials, in which case our development plans will be delayed, which could materially harm our business. We are currently conducting, and we or our current or any future collaborators may in the future conduct, one or more of our clinical trials for cretostimogene or any future product candidate outside the United States. The acceptance of study data from clinical trials conducted outside the United States or another jurisdiction by the FDA or comparable foreign regulatory authority may be subject to certain conditions or may not be accepted at all. For example, in cases where data from foreign clinical trials are intended to serve as the sole basis for regulatory approval in the United States, the FDA will generally not approve the application on the basis of foreign data alone unless the data are applicable to the U. S. population and U. S. medical practice; the trials were performed by clinical investigators of recognized competence and pursuant to GCP regulations; and the data may be considered valid without the need for an on- site inspection by the FDA, or if the FDA considers such inspection to be necessary, the FDA is able to validate the data through an on- site inspection or other appropriate means. In addition, even where the foreign study data are not intended to serve as the sole basis for approval, if the relevant study was not conducted pursuant to an IND, the FDA will not accept the data as support for a marketing application unless the study was conducted in accordance with GCP requirements and the FDA is able to validate the data from the study through an onsite inspection if deemed necessary. Many foreign regulatory authorities have similar requirements for clinical data gathered outside of their respective jurisdictions. There can be no assurance that the FDA or any comparable foreign regulatory authority will accept data from trials conducted outside of the United States or the applicable jurisdiction. If the FDA or any comparable foreign regulatory authority does not accept such data from our clinical trials of cretostimogene or any future product candidate, it would likely result in the need for additional clinical trials, which would be costly and time- consuming and delay or permanently halt our development of such product candidate. Conducting clinical trials outside the United States also exposes us to additional risks, including risks associated with: • additional foreign regulatory requirements; • foreign exchange fluctuations; • compliance with foreign manufacturing, customs, shipment, and storage requirements; • inconsistent standards for reporting and evaluating clinical data and adverse events; • diminished protection of intellectual property in some countries; and • public health concerns or political instability, civil unrest, war or similar events that may jeopardize our ability to commence, conduct or complete a clinical trial and evaluate resulting data. ~~Interim, topline and preliminary data from our clinical trials and preclinical studies that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data.~~ From time to time, we may publicly disclose interim, topline or preliminary data from our clinical trials and preclinical studies, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial **. For example, topline data from the Phase 3 BOND- 003 Cohort C trial that was presented as a late- breaking abstract at the 2024 SUO Annual Meeting showed that cretostimogene, as a single agent, achieved a 74. 5 % CR at any time in high- risk BCG- unresponsive NMIBC, which was updated to 75. 5 % at the 2025 Annual EAU Congress** . 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 interim, topline or preliminary results that we report may differ from future results of the same studies or trials, or different conclusions or considerations may qualify such results once additional data have been received and fully evaluated **, including with respect to the topline data from the Phase 3 BOND- 003 Cohort C trial** . Topline and preliminary data also remain subject to audit and verification procedures that may result, in the final data being materially different from the topline or preliminary data we previously published. As a result,

topline and preliminary data should be viewed with caution until the final data are available. Interim data from clinical trials that we may complete are further 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. Adverse differences between interim, topline or preliminary data and final data could significantly harm our business prospects. Further, disclosure of interim data by us or by our competitors could result in volatility in the price of our common stock. In addition, others, including regulatory authorities, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate or product and our company in general. Moreover, the information we choose to publicly disclose regarding a particular study or clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure, and any information we determine not to disclose may ultimately be deemed significant with respect to future decisions, conclusions, views, activities or otherwise regarding a particular drug, product candidate or our business. If the interim, topline or preliminary data that we report differ from actual results, **including with respect to the topline data we reported from the Phase 3 BOND- 003 Cohort C trial,** or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize cretostimogene and any future product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. Changes in methods of the manufacturing or formulation of cretostimogene or any future product candidates may result in additional costs or delay. As cretostimogene and any future product candidates progress through clinical trials to regulatory 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 safety, efficacy, yield and manufacturing batch size, minimize costs and achieve consistent quality and results. There can be no assurance that any future manufacturing or formulation changes we may make will achieve their intended objectives, and such changes may also cause cretostimogene or any future product candidates to perform differently and affect the results of future clinical trials conducted with the altered materials. Such changes or related unfavorable clinical trial results or changes in the CMOs we use to manufacture cretostimogene or any future product candidates could delay initiation or completion of clinical trials, require the conduct of bridging studies or additional clinical trials or the repetition of one or more studies or clinical trials, increase development costs, delay or prevent potential regulatory approval and jeopardize our ability to commercialize cretostimogene or any future product candidates, if approved, and generate revenue. A Breakthrough Therapy designation from the FDA may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that cretostimogene or any future product candidates will receive FDA approval. We have obtained Breakthrough Therapy designation from the FDA for cretostimogene for the treatment of BCG- unresponsive, high - risk NMIBC ~~patients~~ with carcinoma in- situ with or without Ta or T1 ~~papillary~~ tumors to improve ~~complete response (~~ CR ~~)~~ and for cretostimogene in combination with pembrolizumab for the treatment of NMIBC unresponsive to BCG, and we may seek additional Breakthrough Therapy designations for cretostimogene or for any future product candidates where we believe the clinical data support such a designation. A " Breakthrough Therapy " is defined as a drug or biologic that is intended, alone or in combination with one or more other drugs or biologics, to treat a serious or life- threatening disease or condition, where preliminary clinical evidence indicates that the drug or biologic may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For product candidates that have been designated as Breakthrough Therapies, increased interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Biologics designated as Breakthrough Therapies also receive the same benefits associated with fast track designation, including eligibility for rolling review of a submitted BLA, if the relevant criteria are met. Designation as a Breakthrough Therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a Breakthrough Therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy ~~Designation~~ **designation** for cretostimogene or any future product candidate may not result in a faster development process, review or approval compared to biologics considered for approval under standard FDA review procedures and does not ensure ultimate approval by the FDA. In addition, though cretostimogene currently qualifies as a Breakthrough Therapy for the treatment of NMIBC unresponsive BGC, the FDA may later decide that cretostimogene no longer meets the conditions for qualification and rescind the designation. Fast track designation by the FDA for cretostimogene may not lead to a faster development or regulatory review or approval process, and does not increase the likelihood that cretostimogene or any future product candidate which may receive fast track designation will receive regulatory approval. The FDA has granted a fast track designation for cretostimogene for the treatment of BCG- unresponsive, high - risk NMIBC ~~patients~~ with carcinoma in- situ with or without Ta or T1 ~~papillary~~ tumors to improve CR, and we may seek fast track designations for other indications or future product candidates. The fast track program is intended to expedite or facilitate the process for reviewing product candidates that meet certain criteria. Specifically, biologics are eligible for fast track designation if they are intended, alone or in combination with one or more drugs or biologics, to treat a serious or life- threatening disease or condition and demonstrate the potential to address unmet medical needs for the disease or condition. Fast track designation applies to the combination of the product candidate and the specific indication for which it is being studied. The sponsor of a fast track product candidate has opportunities for more frequent interactions with the applicable FDA review team during product development and, once a BLA is submitted, the application may be eligible for priority review. A BLA submitted for a fast track product candidate may also be eligible for rolling review, where the FDA may consider for review sections of the BLA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the BLA, the FDA agrees to accept sections of the BLA and determines that the schedule is acceptable, and the Sponsor pays any required user fees upon submission of the first section of the BLA. The FDA has broad

discretion whether or not to grant this designation. Even if we believe a particular product candidate or development program is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Although we have received fast track designation for cretostimogene for the treatment of BCG- unresponsive, high - risk NMIBC ~~patients~~ with carcinoma in- situ with or without Ta or T1 ~~papillary~~ tumors to improve CR, and even if we receive additional fast track designations for other indications or any future product candidates, such product candidates may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may also withdraw fast track designation if it believes that the designation is no longer supported by data from our clinical development program. Furthermore, such a designation does not increase the likelihood that cretostimogene or any future product candidate that may be granted fast track designation will receive marketing approval in the United States. Many product candidates that have received fast track designation have ultimately failed to obtain approval. We may attempt to secure approval from the FDA through the use of the accelerated approval pathway. If we are unable to obtain such approval, we may be required to conduct additional clinical trials beyond those that we contemplate, which could increase the expense of obtaining, and delay the receipt of, necessary regulatory approvals. Even if we receive accelerated approval from the FDA, if our confirmatory trials do not verify clinical benefit, or if we do not comply with rigorous post- marketing requirements, the FDA may seek to withdraw any accelerated approval we have obtained. We may in the future seek an accelerated approval for cretostimogene or our future product candidates. Under the accelerated approval program, the FDA may grant accelerated approval to a product candidate designed to treat a serious or life-threatening condition that provides meaningful therapeutic benefit over available therapies upon a determination that such product candidate has an effect on a surrogate endpoint or intermediate clinical endpoint that is reasonably likely to predict clinical benefit. The FDA considers a clinical benefit to be a positive therapeutic effect that is clinically meaningful in the context of a given disease, such as irreversible morbidity or mortality. For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. An intermediate clinical endpoint is a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality that is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit. The accelerated approval pathway may be used in cases in which the advantage of a new drug over available therapy may not be a direct therapeutic advantage, but is a clinically important improvement from a patient and public health perspective. If granted, accelerated approval is usually contingent on the sponsor' s agreement to conduct, in a diligent manner, additional post- approval confirmatory studies to verify and describe the drug' s clinical benefit. If such confirmatory studies fail to confirm the drug' s clinical benefit or are not completed in a timely manner, the FDA may withdraw its approval of the drug on an expedited basis. In addition, ~~in December 2022, the Food and Drug Omnibus Reform Act of 2022 was enacted, which, among other things, provided the FDA new statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval and additional oversight over confirmatory trials. Under these provisions,~~ the FDA may, among other things, require a sponsor of a product seeking accelerated approval to have a confirmatory trial underway prior to such approval being granted. Prior to seeking approval for cretostimogene or any future product candidate we intend to seek feedback from the FDA and will otherwise evaluate our ability to seek and receive accelerated approval. There can be no assurance that after our evaluation of the feedback and other factors we will decide to pursue or submit a BLA for accelerated approval or obtain any other form of expedited development, review, or approval. Furthermore, if we decide to submit an application for accelerated approval for cretostimogene or any future product candidate, there can be no assurance that such submission or application will be accepted or that any expedited development, review, or approval will be granted on a timely basis, or at all. The FDA could also require us to conduct further studies prior to considering our application or granting approval of any type. A failure to obtain accelerated approval or any other form of expedited development, review, or approval for cretostimogene or any future product candidate would result in a longer time period to commercialization of such product candidate, if any, could increase the cost of development of such product candidate, and could harm our competitive position in the marketplace. Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, approved or commercialized in a timely manner or at all, which could negatively impact our business. The ability of the FDA and other government agencies to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory and policy changes, a government agency' s ability to hire and retain key **and sufficient** personnel and accept the payment of user fees, and other events that may otherwise affect the government agency' s ability to perform routine functions. Average review times at the FDA and other government agencies have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new biologics or modifications to **be** approved or licensed biologics to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. Separately, in response to the COVID- 19 pandemic, the FDA postponed most inspections of domestic and foreign manufacturing facilities at various points. Even though the FDA has since resumed standard inspection operations of domestic facilities where feasible, future pandemics may lead to similar inspectional or administrative delays. If any future prolonged government shutdown occurs **, there are personnel shortages at the FDA or other regulatory agencies** , or if global health concerns prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business. ~~Risks Related to Our Reliance on Third Parties We rely on third parties to conduct our clinical trials and preclinical studies. If these third parties do~~

~~not successfully carry out their contractual duties, comply with applicable regulatory requirements, or meet expected deadlines, cretostimogene or any future product candidate and our ability to seek or obtain regulatory approval for or commercialize cretostimogene or any future product candidates may be delayed.~~ We are dependent on third parties to conduct our clinical trials and preclinical studies. Specifically, we rely on, and intend to continue to rely on, medical institutions, clinical investigators, CROs and consultants to conduct our preclinical studies and clinical trials in accordance with our clinical protocols and regulatory requirements. These CROs, investigators and other third parties play a significant role in the conduct and timing of these trials and subsequent collection and analysis of data. While we have and will have agreements governing the activities of our third- party contractors, we have limited influence over their actual performance. Nevertheless, we are responsible for ensuring that each of our clinical trials is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards and requirements, and our reliance on our CROs and other third parties does not relieve us of our regulatory responsibilities. In addition, we and our CROs are required to comply with ~~Good Laboratory Practice (~~ GLP ~~)~~ requirements for certain preclinical studies, as well as GCP requirements, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for cretostimogene and any future product candidates in clinical development. Regulatory authorities enforce these GCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our CROs or trial sites fail to comply with applicable GLP or GCP or other requirements, the clinical data generated in our preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional preclinical studies or clinical trials before approving our marketing applications, if ever. Further, our clinical trials must be conducted with products produced in accordance with cGMP regulations. Failure to comply with these regulations may require us to repeat clinical trials, which would delay the regulatory approval process. There is no guarantee that any of our CROs, investigators or other third parties will devote adequate time and resources to such trials or studies or perform as contractually required. If any of these third parties fail to meet expected deadlines, adhere to our clinical protocols or meet regulatory requirements, or otherwise perform in a substandard manner, our clinical trials may be extended, delayed or terminated. In addition, many of the third parties with whom we contract may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials or other development activities that could harm our competitive position. In addition, principal investigators for our clinical trials have served and may in the future serve as scientific advisors or consultants to us from time to time and may receive cash or equity compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA or comparable foreign regulatory authorities conclude that the financial relationship may have affected the interpretation of the study, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA or comparable foreign regulatory authorities of any BLA we submit or any comparable submission. Any such delay or rejection could prevent us from receiving regulatory approval for, or commercializing cretostimogene and any future product candidates. Our CROs have the right to terminate their agreements with us in the event of an uncured material breach and under other specified circumstances. If any of our relationships with these third parties terminate, we may not be able to enter into arrangements with alternative third parties on commercially reasonable terms, in a timely manner or at all. Switching or adding additional CROs, investigators and other third parties involves additional cost and requires our 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 work to carefully manage our relationships with our CROs, investigators and other third parties, 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, results of operations and prospects **. We rely on third parties for the manufacture and shipping of cretostimogene for clinical development and expect to continue to do so for the foreseeable future. This reliance on third parties increases the risk that we will not have sufficient quantities of cretostimogene or future product candidates or such quantities at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts** . We do not own or operate manufacturing facilities and have no plans to develop our own clinical or commercial- scale manufacturing capabilities. We rely on a third- party manufacturer for the production of cretostimogene and a third- party manufacturer for the production of DDM, and expect to continue to rely on third- party manufacturers for commercial manufacture if cretostimogene or any future product candidates receive regulatory approval. The facilities used by third- party manufacturers to manufacture cretostimogene or any future product candidate must be approved for the manufacture of such product candidate by the FDA and any comparable foreign regulatory authority pursuant to inspections that will be conducted after we submit a BLA to the FDA or any comparable submission to a foreign regulatory authority. We do not control the manufacturing process of, and are completely dependent on, third- party manufacturers for compliance with cGMP requirements for manufacture of products. If these third- party manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or any comparable foreign regulatory authority, they will not be able to secure and / or maintain regulatory approval for their manufacturing facilities. In addition, we have no control over the ability of third- party manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or any comparable foreign regulatory authority does not approve these facilities for the manufacture of cretostimogene or any future product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market cretostimogene or any future product candidates, if approved. Our failure, or the failure of our third- party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or recalls of cretostimogene or any future product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of cretostimogene or any future product

candidates. Our or a third party' s failure to execute on our manufacturing requirements on commercially reasonable terms, in a timely manner and in compliance with cGMP or other regulatory requirements could adversely affect our business in a number of ways, including: • an inability to initiate or continue clinical trials of cretostimogene or any future product candidates, or a hold on clinical trials of cretostimogene or any future product candidates; • delay in submitting regulatory applications, or receiving regulatory approvals, for cretostimogene or any future product candidates; • subjecting third- party manufacturing facilities to additional inspections by regulatory authorities; • requirements to cease development or to recall batches of cretostimogene or any future product candidates; and • in the event of approval to market and commercialize cretostimogene or any future product candidates, an inability to meet commercial demands for cretostimogene or any future product candidates. For example, our IND for cretostimogene was previously placed on partial clinical hold by the FDA that was lifted in March 2020, primarily due to CMC- related issues attributable to product supplied by our prior third- party manufacturer, who was purchased by another third- party supplier, resulting in clinical development delays. In addition, **while we are in the process of establishing long- term commitment or supply agreements for the commercial supply of cretostimogene,** we do not **currently** have any **such** long- term commitments or supply agreements with our third- party manufacturers. We may be unable to establish any long- term supply agreements with third- party manufacturers or to do so on acceptable terms or at all, which increases the risk of failing to timely obtain sufficient quantities of cretostimogene or such quantities at an acceptable cost. Even if we are able to establish agreements with third- party manufacturers, reliance on third- party manufacturers entails additional risks, including: • failure of third- party manufacturers to comply with regulatory requirements and maintain quality assurance; • breach of the manufacturing agreement by the third party; • failure to manufacture our product according to our specifications; • failure to obtain adequate raw materials and other materials required for manufacturing; • failure to **devote appropriate resources to manufacture our product, or** manufacture our product according to our schedule or at all; • failure to successfully scale up manufacturing capacity, if required; • misappropriation of our proprietary information, including our trade secrets and know- how; and • termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us **. Despite our efforts, we may encounter unforeseen challenges and risks that could impact the effectiveness of our supply chain enhancements. These challenges may include, but are not limited to, regulatory hurdles, supply chain disruptions, and potential delays in the manufacturing and distribution processes. As a result, our ability to ensure a reliable and efficient supply chain for cretostimogene may be compromised, which could adversely affect our business operations and financial performance** . Further, cretostimogene and any future product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. We also rely on a third party to store and transport cretostimogene at temperatures within a certain range, which is known as " strict cold chain " storage and transportation. Any failure by this third party to store or transport cretostimogene at the appropriate temperature could impair the quality of cretostimogene or cause cretostimogene to become unsuitable for use, which could result in lost inventories, increased costs or delays in clinical development. Any performance failure on the part of our existing or future manufacturers, suppliers or vendors could delay clinical development or regulatory approval, and any related remedial measures may be costly or time consuming to implement. We do not currently have arrangements in place for redundant manufacturing of cretostimogene and DDM. In addition, there are a limited number of manufacturers capable of manufacturing viral therapies such as cretostimogene, and therefore any need to switch third- party manufacturers may result in development and commercialization delays and increase our operating costs. If our existing or future third- party manufacturers and suppliers cannot perform as agreed or cannot fulfill our commercial supply requirements, we may be required to replace such manufacturers or suppliers and we may be unable to replace them on a timely basis or at all. If we later switch third- party manufacturers, we may be unable to demonstrate comparability between lots produced previously and those produced by such new third- party manufacturers, in which case we may be required to gather additional data utilizing material produced by such new third- party manufacturers before we are able to submit a BLA for cretostimogene, if ever. In addition, our current and anticipated future dependence upon others for the manufacture of cretostimogene or any future product candidates may adversely affect our future profit margins and our ability to commercialize any products that receive regulatory approval on a timely and competitive basis. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor or other third party will discover them or that our trade secrets will be misappropriated or disclosed. Because we currently rely on third parties to manufacture cretostimogene and to perform quality testing, we must, at times, share our proprietary technology and confidential information, including trade secrets, with them. We seek to protect our proprietary technology, in part, by entering into confidentiality agreements, and, if applicable, material transfer agreements, collaborative research agreements, consulting agreements or other similar agreements with our collaborators, advisors, employees and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors or other third parties, are intentionally or inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets and despite our efforts to protect our trade secrets, a competitor' s or other third party' s discovery of our proprietary technology and confidential information or other unauthorized use or disclosure of such technology or information would impair our competitive position and may have a material adverse effect on our business, financial condition, results of operations and prospects. We have entered into, and may in the future enter into, collaboration agreements and strategic alliances to maximize the potential of cretostimogene, and we may not realize the anticipated benefits of such collaborations or alliances. We may continue to form collaborations or alliances in the future with respect to cretostimogene or any future product candidates, but may be unable to do so or to realize the potential benefits of such transactions, which may cause us to alter or delay our development and commercialization plans. We have entered into, and may in the future seek to enter into, collaborations, joint ventures, licenses

and other similar arrangements for the development or, if approved, commercialization of cretostimogene and any future product candidates due to capital costs required to develop or commercialize such product candidates or otherwise. For example, we have entered into license and collaboration agreements with Lepu Biotech Co., Ltd. (Lepu) and Kissei Pharmaceutical Co., Ltd. (Kissei), pursuant to which we granted Lepu exclusive rights to develop and commercialize cretostimogene and / or DDM in Greater China, including Hong Kong and Macau (the Lepu Territory), and granted Kissei exclusive rights to develop and commercialize cretostimogene in combination with DDM in Japan and other Asian counties (excluding the Lepu territory). We may not be successful in our efforts to establish or maintain such collaborations because our research and development pipeline may be insufficient, future product candidates may be deemed to be at too early of a stage of development for collaborative effort or third parties may not view cretostimogene or any future product candidates as having the requisite potential to demonstrate safety, purity and potency (or efficacy), or significant commercial opportunity. In addition, we face significant competition in seeking appropriate strategic partners, and the negotiation process can be time- consuming and complex. Even if we are successful in our efforts to establish or maintain such collaborations, the terms that we agree upon may not be favorable to us. As a result, we may need to relinquish valuable rights to our future revenue streams, research programs, intellectual property, cretostimogene or any future product candidates, or grant licenses on terms that may not be favorable to us, as part of any such arrangement, and such arrangements may restrict us from entering into additional agreements with other potential collaborators. In addition, our current collaborations limit, and potential future collaborations may limit, our control over the amount and timing of resources that our collaborators will dedicate to the development or commercialization of cretostimogene or any future product candidates. Our ability to generate revenue from these arrangements will depend on any current or future collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a collaboration, license, or strategic transaction, we will achieve an economic benefit that justifies such transaction, and such transaction may not yield additional development product candidates for our pipeline. Furthermore, we may not be able to maintain such collaborations if, for example, the development or approval of cretostimogene or any future product candidate is delayed, the safety of any such product candidate is questioned, or the sales of cretostimogene, if approved, or an approved future product candidate, are unsatisfactory. In addition, our current collaborations are, and potential future collaborations may be, terminable by our strategic partners, and we may not be able to adequately protect our rights under these agreements. Furthermore, strategic partners may negotiate for certain rights to control decisions regarding the development and, if approved, commercialization of cretostimogene or any future product candidates, and may not conduct those activities in the same manner as we do. Any termination of collaborations we enter into in the future, or any delay in entering into collaborations related to cretostimogene or any future product candidates, could delay the development and, if approved, commercialization of such product candidates, and reduce their competitiveness if they reach the market, which could have a material adverse effect on our business, financial condition, results of operations and prospects. ~~Risks Related to Commercialization of Cretostimogene and any Future Product Candidates~~Even if we receive regulatory approval for cretostimogene or any future product candidates, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense. Any regulatory approvals that we may receive for cretostimogene or any future product candidates will require the submission of reports to regulatory authorities, subject us to surveillance to monitor the safety and efficacy of the product, may contain significant limitations related to use restrictions for specified age groups, warnings, precautions or contraindications, and may include burdensome post- approval study or risk management requirements. For example, the FDA may require a REMS as a condition of approval of cretostimogene or any future product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. In addition, if the FDA or a comparable foreign regulatory authority approves cretostimogene or any future product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with cGMPs and GCP requirements for any clinical trials that we conduct post- approval. Manufacturers of approved products and their facilities are subject to continual review and periodic, unannounced inspections by the FDA and other regulatory authorities for compliance with cGMP regulations and standards. Failure to comply with regulatory requirements or later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing processes, may result in, among other things: • restrictions on the marketing or manufacturing of our products, withdrawal of the product from the market or voluntary or mandatory product recalls; • restrictions on product distribution or use, or requirements to conduct post- marketing studies or clinical trials; • restrictions on our ability to conduct clinical trials, including full or partial clinical holds on ongoing or planned trials; • fines, restitutions, disgorgement of profits or revenue, warning letters, untitled letters, adverse publicity requirements or holds on clinical trials; • refusal by the FDA or other regulatory authorities to approve pending applications or supplements to approved applications submitted by us or suspension or revocation of approvals; • product seizure or detention, or refusal to permit the import or export of our products; and • injunctions and the imposition of civil or criminal penalties. The occurrence of any event or penalty described above may inhibit our ability to commercialize cretostimogene or any future product candidates and generate revenue and could require us to expend significant time and resources in response and could generate negative publicity. The FDA' s and other regulatory authorities' policies may change and additional government regulations may be promulgated that could prevent, limit or delay marketing authorization of cretostimogene or any future product candidates. We also 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 be subject to enforcement action and we may not achieve or sustain profitability. The

FDA and other regulatory agencies actively enforce the laws and regulations prohibiting the promotion of off- label uses. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, such as cretostimogene or any future product candidates, if approved. In particular, a product may not be promoted for uses that are not approved by the FDA or such other regulatory agencies as reflected in the product' s approved labeling. If we receive regulatory approval for cretostimogene or any future product candidates, physicians may nevertheless prescribe it to their patients in a manner that is inconsistent with the approved label. If we are found to have promoted such off- label uses, we may become subject to significant liability. The U. S. federal government has levied large civil and criminal fines against companies for alleged improper promotion of off- label use and has enjoined several companies from engaging in off- label promotion. The government has also required companies to enter into consent decrees or imposed permanent injunctions under which specified promotional conduct is changed or curtailed. If we cannot successfully manage the promotion of cretostimogene or any future product candidates, if approved, we could become subject to significant liability, which would materially adversely affect our business and financial condition. Any product candidates for which we intend to seek approval as biologic products may face competition sooner than anticipated. The **ACA** ~~Patient Protection and Affordable Care Act~~, signed into law on March 23, 2010, includes a subtitle called the ~~Biologics Price Competition and Innovation Act of 2009 (~~BPCIA ~~)~~, which created an abbreviated approval pathway for biological products that are biosimilar to or interchangeable with an FDA- licensed reference biological product. Under the BPCIA, an application for a biosimilar product may not be submitted to the FDA until four years following the date that the reference product was first licensed by the FDA. In addition, the approval of a biosimilar product may not be made effective by the FDA until 12 years from the date on which the reference product was first licensed. 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 preclinical data and data from adequate and well- controlled clinical trials to demonstrate the safety, purity and potency (or efficacy) of its product. We believe that any cretostimogene or any future product candidates, if approved as a biological product under a BLA, should qualify for the 12- year period of exclusivity. However, there is a risk 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, could be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non- biological products will depend on a number of marketplace and regulatory factors continue to develop. The commercial success of cretostimogene or any future product candidates will depend upon the degree of market acceptance of such product candidates by physicians, patients, healthcare payors, and others in the medical community. Cretostimogene and any future product candidates may not be commercially successful. Even if cretostimogene or any future product candidates receive regulatory approval, they may not gain market acceptance among physicians, patients, healthcare payors, or the medical community. The commercial success of cretostimogene or any future product candidates will depend significantly on the broad adoption and use of the resulting product by these individuals and organizations for approved indications. In particular, given a significant portion of large urology practices are concentrated in a relatively small number of urology physician groups, market adoption by such groups will be an important factor in potential commercial success. The degree of market acceptance of our products will depend on a number of factors, including: • demonstration of clinical efficacy and safety, including as compared to any more- established products; • the indications for which cretostimogene or any future product candidates are approved, if any; • the limitation of our targeted patient population and other limitations or warnings contained in any FDA- approved labeling; • acceptance of a new drug for the relevant indication by healthcare providers and their patients; • the pricing and cost- effectiveness of our products, as well as the cost of treatment with our products in relation to alternative treatments and therapies; • our ability to obtain and maintain sufficient third- party coverage and adequate reimbursement from government healthcare programs, including Medicare and Medicaid, private health insurers and other third- party payors; • the willingness of patients to pay all, or a portion of, out- of- pocket costs associated with our products in the absence of sufficient third- party coverage and adequate reimbursement; • any restrictions on the use of our products, and the prevalence and severity of any adverse effects; • potential product liability claims; • the timing of market introduction of our products as well as availability, safety and efficacy of competitive drugs; • the effectiveness of our or any current or future collaborators' sales and marketing strategies; and • unfavorable publicity relating to the product. If cretostimogene or any future product candidates is approved but does not achieve an adequate level of acceptance by physicians, hospitals, healthcare payors or patients, we may not generate sufficient revenue from that product and may not become or remain profitable. Our efforts to educate the medical community and third- party payors regarding the benefits of our products may require significant resources and may never be successful. The successful commercialization of cretostimogene or any future product candidates, if approved, will depend in part on the extent to which governmental authorities and health insurers establish coverage, adequate reimbursement levels and favorable pricing policies. Failure to obtain or maintain coverage and adequate reimbursement for our products could limit our ability to market those products and decrease our ability to generate revenue. The availability of coverage and the adequacy of reimbursement by governmental healthcare programs such as Medicare and Medicaid, private health insurers and other third- party payors are essential for most patients to be able to afford prescription medications such as cretostimogene or any future product candidates, if approved. Our ability to achieve coverage and acceptable levels of reimbursement for our products by third- party payors will have an effect on our ability to successfully commercialize those products. Accordingly, we will need to successfully implement a coverage and reimbursement strategy for any approved product candidate. Even if we obtain coverage for a given product by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. If we participate in the Medicaid Drug Rebate Program or other governmental pricing programs, in certain circumstances, our products would be subject to ceiling prices set by such programs, which could reduce the revenue we may generate from any such products. Participation in such programs would also expose us to the risk of

significant civil monetary penalties, sanctions and fines should we be found to be in violation of any applicable obligations thereunder. Third- party payors increasingly are challenging prices charged for biopharmaceutical products and services, and many third- party payors may refuse to provide coverage and reimbursement for particular drugs when an equivalent generic drug or a less expensive therapy is available. It is possible that a third- party payor may consider our products as substitutable and offer to reimburse patients only for the less expensive product. Even if we are successful in demonstrating improved efficacy or improved convenience of administration with our products, pricing of existing drugs may limit the amount we will be able to charge for our products. These payors may deny or revoke the reimbursement status of a given product or establish prices for new or existing marketed products at levels that are too low to enable us to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize our products and may not be able to obtain a satisfactory financial return on products that we may develop. There is significant uncertainty related to third- party payor coverage and reimbursement of newly approved products. In the United States, third- party payors, including private and governmental payors, such as the Medicare and Medicaid programs, play an important role in determining the extent to which new drugs will be covered. Some third- party payors may require pre- approval of coverage for new or innovative devices or drug therapies before they will reimburse healthcare providers who use such therapies. It is difficult to predict at this time what third- party payors will decide with respect to the coverage and reimbursement for cretostimogene or any future product candidates. Obtaining and maintaining reimbursement status is time- consuming, costly and uncertain. The Medicare and Medicaid programs increasingly are used as models for how private payors and other governmental payors develop their coverage and reimbursement policies for drugs. However, no uniform policy for coverage and reimbursement for products exists among third- party payors in the United States. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Furthermore, rules and regulations regarding reimbursement change frequently, and, in some cases, at short notice, and we believe that changes in these rules and regulations are likely. 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. Additionally, separate reimbursement for the product itself or the treatment or procedure in which the product is used may not be available, which may impact physician utilization. Outside the United States, international operations are generally subject to extensive governmental price controls and other market regulations, and we believe the increasing emphasis on cost- containment initiatives in Europe and other countries has and will continue to put pressure on the pricing and usage of cretostimogene or any future product candidates, if approved in these jurisdictions. In many countries, the prices of medical products are subject to varying price control mechanisms as part of national health systems. Other countries allow companies to fix their own prices for medical products but monitor and control company profits. Additional foreign price controls or other changes in pricing regulation could restrict the amount that we are able to charge for our products. Accordingly, in markets outside the United States, the reimbursement for our products may be reduced compared with the United States and may be insufficient to generate commercially reasonable revenue and profits. Moreover, increasing efforts by governmental and third- party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs, surgical procedures and other treatments in particular, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products. See the section titled " Risk Factors — Risks Related to Our Business Operations and Industry — Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize cretostimogene or any future product candidates and may adversely affect the prices we may set " for additional related information. ~~" We face significant competition from entities that have developed or may develop product candidates for cancer, including companies developing novel treatments and technology platforms. If our competitors develop and commercialize their product candidates more rapidly than we do, or their technologies or product candidates are more effective, safer, or less expensive than cretostimogene or any future product candidates we develop, our business and our ability to develop and successfully commercialize products may be adversely affected.~~ The biopharmaceutical industry is characterized by rapid advancing technologies, intense competition and a strong emphasis on proprietary and novel products and product candidates. Our competitors have developed, are developing or may develop products, product candidates and processes competitive with cretostimogene. Cretostimogene and any future product candidates we successfully develop and commercialize will compete with existing therapies and new therapies that may become available in the future. We believe that a significant number of products are currently under development, and may become commercially available in the future, for the treatment of indications for which we are developing cretostimogene. In particular, there is intense competition in the oncology field. Our competitors include larger and better- funded pharmaceutical, biopharmaceutical, biotechnological and therapeutics companies. Moreover, we may also compete with universities and other research institutions that may be active in oncology research and could be in direct competition with us. We also compete with these organizations to recruit management, scientists and clinical development personnel, and our inability to compete successfully could negatively affect our level of expertise and our ability to execute our business plan. We will also face competition in establishing clinical trial sites, enrolling patients for clinical trials and identifying and in- licensing intellectual property related to future product candidates, as well as entering into collaborations, joint ventures, license agreements and other similar arrangements. Smaller or early- stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. If cretostimogene

or any future product candidates are approved, they will compete with surgery, radiation, and drug therapy, including chemotherapy, BCG, hormone therapy, biologic therapy, such as monoclonal and bispecific antibodies, antibody- drug conjugates, radiopharmaceuticals, immunotherapy, cell- based therapy, and targeted therapy, or a combination of any such methods, either approved or under development, which are intended to treat the same indications that we are targeting or may target, including through approaches that may prove to be more effective, have fewer side effects, be less costly to manufacture, be more convenient to administer or have other advantages over cretostimogene and any future product candidates. To the extent Merck & Co. (Merck) or another manufacturer increases the supply of BCG, there may be less demand for alternative treatments such as cretostimogene in BCG- naïve or BCG- exposed patients. There are numerous companies that have commercialized or are developing treatments for NMIBC that we will compete with, including Bristol Meyers Squibb, enGene Inc., Gilead Sciences, Inc., Hoffman- La Roche AG (Roche), ImmunityBio Inc., Johnson & Johnson Inc., Merck, Protara Therapeutics, Inc., Pfizer, Inc. and UroGen Pharma, Inc. **For example, on October 15, 2024, UroGen announced that the FDA accepted UroGen' s NDA for UGN- 102 (intravesical mitomycin / sterile hydrogel) in LG- IR- NMIBC, and set a PDUFA action date of June 13, 2025. In addition, Johnson & Johnson announced on January 15, 2025 that it initiated the submission of an NDA with the FDA for TAR- 200 for the treatment of patients with BCG- unresponsive high- risk non- muscle- invasive bladder cancer (HR- NMIBC) with CIS, with or without papillary tumors. If UGN- 102 or TAR- 200 receives FDA approval and enter the bladder cancer market prior to the approval of cretostimogene, the market for cretostimogene may be adversely affected and our opportunity to generate revenue from the sale of cretostimogene, if approved, could be adversely affected.** Many of our competitors have significantly greater financial, technical, manufacturing, marketing, sales and supply resources or experience than we do. If we successfully obtain approval for cretostimogene or any future product candidate, we will face competition based on many different factors, including the safety and effectiveness of our product candidates, the ease with which our product candidates can be administered, and the extent to which patients accept relatively new routes of administration, the timing and scope of regulatory approvals for these product candidates, the availability and cost of manufacturing, marketing and sales capabilities, price, reimbursement coverage, and patent position. Competing products could present superior treatment alternatives, including by being more effective, safer, more convenient, less expensive, or marketed and sold more effectively than any products we may develop. Competitive products may make cretostimogene or any future product candidates we develop obsolete or noncompetitive before we recover the expense of their development and commercialization. If we are unable to compete effectively, our opportunity to generate revenue from the sale of cretostimogene or any future product candidates we may develop, if approved, could be adversely affected. If the market opportunities for cretostimogene or any future product candidates are smaller than we believe they are, our revenue may be adversely affected, and our business may suffer. Cancer therapies are defined by lines of therapy as well as by treatment- naïve or previously- treated status. Often the initial approval for a new therapy is in later lines and subsequent approval in an earlier line may not be feasible. When cancer is detected early enough, first line therapy is sometimes adequate to cure the cancer or prolong life without a cure. Whenever first line therapy, including surgery, radiation therapy, targeted therapy, immunotherapy, chemotherapy, hormone therapy, or a combination of these, proves unsuccessful, second line therapy may be administered. Second line therapies often consist of additional chemotherapy, radiation, antibody drugs, tumor targeted small molecules, or a combination of these. Third line therapies can include antibody and small molecule targeted therapies, more invasive forms of surgery, and new technologies. In markets with approved therapies, there is no guarantee that cretostimogene or any future product candidate, even if approved, would be approved for second line or first line therapy. This could limit our potential market opportunity. In addition, we may have to conduct additional clinical trials prior to gaining approval for second line or first line therapy. Our projections of both the number of people who have the cancers we are targeting, as well as the subset of people with these cancers in a position to receive later stage therapy and who have the potential to benefit from treatment with cretostimogene or any future product candidate, are based on our beliefs and estimates. These estimates have been derived from a variety of sources, including the scientific literature, publicly available clinical molecular reports, patient foundations, or market research, and may prove to be incorrect. Further, new trials or information may change the estimated incidence or prevalence of these cancers. The number of patients in the United States and other major markets and elsewhere may turn out to be lower than expected, patients may not be otherwise amenable to treatment with our products, or new patients may become increasingly difficult to identify or gain access to, all of which would adversely affect our business, financial condition, results of operations and prospects. Further, even if we obtain significant market share for cretostimogene or any future product candidate, because some of our potential target populations are very small, we may never achieve profitability despite obtaining such significant market share. We ~~currently have no~~ **are in the early stages of building our** marketing and sales organization and have no experience as a company in commercializing products, and we ~~may~~ **will** need to invest significant resources to develop these capabilities. If we are unable to establish marketing and sales capabilities or enter into agreements with third parties to market, sell and distribute our products, we may not be able to generate product revenue. We ~~have no~~ **are currently in the early stages of building our** internal sales ~~,~~ **and** marketing ~~or distribution~~ capabilities **to prepare for the commercialization of cretostimogene** , ~~nor~~ **if approved, and we** have ~~we ever~~ **never** commercialized a product. If cretostimogene or any future product candidate ultimately receives regulatory approval, we must build a marketing and sales organization with technical expertise and supporting distribution capabilities to commercialize each such product in major markets, which will be expensive and time consuming, or collaborate with third parties that have direct sales forces and established distribution systems, either to augment our own sales force and distribution systems or in lieu of our own sales force and distribution systems. For example, if cretostimogene is approved, we will need to scale up a cost- effective and reliable cold chain distribution and logistics network, which we may be unable to accomplish and which will require us to rely on third- party distributors. Failure to scale up our cold chain supply logistics, by us or third parties, could in the future lead to additional manufacturing costs and delays in our ability to supply required quantities for commercial supply. We have no prior experience

as a company with the marketing, sale or distribution of biopharmaceutical products and there are significant risks involved in the building and managing of a sales organization, including our ability to hire, retain and incentivize qualified individuals, generate sufficient sales leads, provide adequate training to sales and marketing personnel and effectively manage a geographically dispersed sales and marketing team. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may not be able to enter into collaborations or hire consultants or external service providers to assist us in sales, marketing and distribution functions on acceptable financial terms, or at all. In addition, our product revenue and our profitability, if any, may be lower if we rely on third parties for these functions than if we were to market, sell and distribute any products that we develop ourselves. We likely will 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. If we are not successful in commercializing our products, either on our own or through arrangements with one or more third parties, we may not be able to generate any future product revenue and we would incur significant additional losses. Our future growth may depend, in part, on our ability to operate in foreign markets, where we would be subject to additional regulatory burdens and other risks and uncertainties. Our future growth may depend, in part, on our ability to develop and commercialize cretostimogene or any future product candidates in foreign markets. We are not permitted to market or promote cretostimogene or any future product candidate before we receive regulatory approval from applicable regulatory authorities in foreign markets, and we may never receive such regulatory approvals for cretostimogene or any future product candidates. To obtain separate regulatory approval in many other countries we must comply with numerous and varying regulatory requirements regarding safety and efficacy and governing, among other things, clinical trials, commercial sales, pricing and distribution of cretostimogene or any future product candidates. Approval procedures may be more onerous than those in the United States and may require that we conduct additional preclinical studies or clinical trials. If we obtain regulatory approval of cretostimogene or any future product candidates and ultimately commercialize our products in foreign markets, we would be subject to additional risks and uncertainties, including: • different regulatory requirements for approval of drugs in foreign countries; • reduced protection for intellectual property rights; • the existence of additional third- party patent rights of potential relevance to our business; • compliance with export control and import laws and regulations and unexpected changes in tariffs, trade barriers and regulatory requirements; • economic weakness, including inflation, or political instability in particular foreign economies and markets; • compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; • foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; • foreign reimbursement, pricing, and insurance regimes; • workforce uncertainty in countries where labor unrest is common; • production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and • business interruptions resulting from geopolitical actions, including war and terrorism, public health pandemics or epidemics, or natural disasters including earthquakes, typhoons, floods and fires. **We have** a relatively limited operating history,have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.We may never generate any revenue or become profitable or,if we achieve profitability,we may not be able to sustain it.Biopharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk.We are a clinical- stage biopharmaceutical company with a relatively limited operating history upon which you can evaluate our business and prospects.We commenced operations in 2010,have no products approved for commercial sale and have not generated any revenue from the sale of our products.To date,we have focused primarily on organizing and staffing our company,business planning,raising capital,conducting research,preclinical studies and clinical trials for our product candidate,cretostimogene,establishing our intellectual property portfolio,establishing arrangements with third parties for the manufacture of cretostimogene and supply of related raw materials,and providing general and administrative support for these operations.We have not yet demonstrated the ability to successfully complete any clinical trial beyond Phase 2,obtain regulatory approvals,manufacture products at commercial scale or arrange for a third party to do so on our behalf,or conduct sales and marketing activities necessary for successful product commercialization.Consequently,any predictions made about our future success or viability may not be as accurate as they could be if we had a history of successfully developing and commercializing biopharmaceutical products.We have incurred significant operating losses since our inception and expect to incur significant losses for the foreseeable future.We do not have any products approved for sale and have not generated any revenue from product sales.If we are unable to successfully develop,obtain requisite approval for and commercialize cretostimogene or any future product candidates,we may never generate revenue.Our net losses were $ **88.0 million and $** 48.6 ~~million and $ 35.4~~ million for the years ended December 31, **2024 and** 2023 ~~and 2022~~ ,respectively.As of December 31, ~~2023~~ **2024** ,we had an accumulated deficit of $ ~~129~~ **218** . ~~9~~ **0** million.Substantially all of our losses have resulted from expenses incurred in connection with our research and development activities and from general and administrative costs associated with our operations.Cretostimogene and any future product candidates will require substantial additional development time and resources before we would be able to ~~apply for or~~ receive regulatory approvals and begin generating revenue from product sales.We expect to continue to incur losses for the foreseeable future,and we anticipate these losses will increase substantially as we continue our development of,seek regulatory approval for and potentially commercialize cretostimogene and any future product candidates,as well as operate as a public company.To become and remain profitable,we must succeed in developing,obtaining regulatory approvals for,and eventually commercializing products that generate significant revenue.This will require us to be successful in a range of challenging activities,including completing clinical trials ~~and preclinical studies~~ of cretostimogene and any future product candidates,acquiring additional product candidates,obtaining regulatory approval for cretostimogene and any future product candidates,and manufacturing,marketing,and selling any products for which we may obtain regulatory approval.We are only in the preliminary stages of ~~most~~ **many** of these activities.We may never succeed in these activities and,even if we do,may never generate revenue that is significant enough to achieve profitability.In addition,we have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by

companies in new and rapidly evolving fields,particularly in the biopharmaceutical industry.Because of the numerous risks and uncertainties associated with biopharmaceutical product development,we are unable to accurately predict the timing or amount of increased expenses or when,or if,we will be able to achieve profitability.Even if we do achieve profitability,we may not be able to sustain or increase profitability on a quarterly or annual basis.Our failure to become and remain profitable may have an adverse effect on the value of our company and could impair our ability to raise capital,expand our business,maintain our research ~~and ,~~ development **and,if approved,commercialization** efforts,diversify our product candidates,achieve our strategic objectives or even continue our operations.A decline in the value of our company could also cause you to lose all or part of your investment.The development of biopharmaceutical product candidates,including conducting preclinical studies and clinical trials,is a very time- consuming,capital- intensive and uncertain process.Our operations have consumed substantial amounts of cash since inception.We expect our expenses to substantially increase in connection with our ongoing activities,particularly as we conduct our ongoing and planned clinical trials of cretostimogene ~~and ,~~ potentially seek regulatory approval for cretostimogene and any future product candidates we may develop **,and build out internal sales and marketing capabilities to prepare for the commercialization of cretostimogene,if approved** .In addition,if we are able to progress cretostimogene through development and commercialization,we expect to be required to make milestone and royalty payments pursuant to various license or collaboration agreements with third parties.If we obtain regulatory approval for cretostimogene or any future product candidates,we also expect to incur significant commercialization expenses related to product manufacturing,marketing,sales,and distribution.Because the outcome of any clinical trial or preclinical study is highly uncertain,we cannot reliably estimate the actual amount of capital necessary to successfully complete the development and commercialization of cretostimogene or any future product candidates.Furthermore,we expect to incur additional costs associated with operating as a public company. **We believe,** ~~Based~~ **based** on our current operating plan, ~~we believe~~ that our existing cash,cash equivalents and marketable securities,will be sufficient to fund our operations ~~through~~ **into the first half of** ~~2027~~ **2028** ~~.In particular,we expect that our existing cash,cash equivalents and marketable securities will allow us to complete the ongoing BOND- 003 and CORE- 001 clinical trials,complete enrollment for the PIVOT- 006 clinical trial,and initiate and report topline data for our planned CORE- 008 clinical trial~~ .We have based these estimates on assumptions that may prove to be wrong,and we could use our capital resources sooner than we currently expect.Our operating plans and other demands on our cash resources may change as a result of many factors currently unknown to us,and we may need to seek additional funds sooner than planned.Our existing capital ~~,~~ may not be sufficient to complete development of cretostimogene,or any future product candidates,and we will require substantial capital in order to advance cretostimogene and any future product candidates through clinical trials,regulatory approval and commercialization.Accordingly,we will need to obtain substantial additional funding in connection with our continuing operations.Our ability to raise additional funds may be adversely impacted by global economic conditions,disruptions to,and volatility in,the credit and financial markets in the United States and worldwide,and diminished liquidity and credit availability.If the equity and credit markets deteriorate,it may make any necessary debt or equity financing more difficult,more costly and more dilutive.If we are unable to raise capital when needed or on attractive terms,we could be forced to delay,reduce or eliminate our research and development programs or any future commercialization efforts,or even cease operations.We expect to finance our cash needs through public or private equity or debt financings or other capital sources,including potential collaborations,licenses,and other similar arrangements.In addition,we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.Attempting to secure additional financing may divert our management from our day- to- day activities,which may adversely affect our ability to develop cretostimogene or any future product candidates.Our future capital requirements will depend on many factors,including,but not limited to:• the initiation,type,number,scope,progress,expansions,results,costs and timing of clinical trials and preclinical studies of cretostimogene and any future product candidates we may choose to pursue,including the costs of modification to clinical development plans based on feedback that we may receive from regulatory authorities and any third- party products used as combination agents in our clinical trials;• the costs and timing of manufacturing for cretostimogene or any future product candidate,including commercial manufacturing at sufficient scale,if any product candidate is approved,including as a result of inflation,any supply chain issues or component shortages;• the costs,timing and outcome of regulatory meetings and reviews of cretostimogene or any future product candidates in any jurisdictions in which we or our current or any future collaborators may seek approval for cretostimogene or any future product candidates;• the costs of obtaining,maintaining,enforcing and protecting our patents and other intellectual property and proprietary rights;• our efforts to enhance operational systems and hire additional personnel to satisfy our obligations as a public company,including enhanced internal control over financial reporting;• the costs associated with hiring additional personnel and consultants as our business grows,including additional executive officers and clinical development,regulatory,chemistry,manufacturing and control (CMC),quality and commercial personnel;• the timing and payment of milestone,royalty or other payments we must make pursuant to our existing and potential future license or collaboration agreements with third parties;• the costs and timing of establishing or securing sales and marketing capabilities if cretostimogene or any future product candidate is approved;• our ability to achieve sufficient market acceptance,coverage and adequate reimbursement from third- party payors and adequate market share and revenue for any approved products;• our ability and strategic decision to develop future product candidates other than cretostimogene,and the timing of such development,if any;• patients' willingness to pay out- of- pocket for any approved products in the absence of coverage and / or adequate reimbursement from third- party payors;• the terms and timing of establishing and maintaining collaborations,licenses and other similar arrangements;and • costs associated with any products or technologies that we may in- license or acquire.Conducting clinical trials and preclinical studies and potentially identifying future product candidates is a time-consuming,expensive and uncertain process that takes years to complete,and we may never generate the necessary data or results required to obtain regulatory approval and commercialize cretostimogene or any future product candidates.If

approved,cretostimogene and any future product candidates may not achieve commercial success ~~. We expect that our commercial revenue,if any,will initially be derived from sales of cretostimogene,which we do not expect to be commercially available for several years,if at all~~ .Accordingly,we will need to continue to rely on additional financing to achieve our business objectives.Adequate additional financing may not be available to us on acceptable terms,or at all,including as a result of financial and credit market deterioration or instability,market- wide liquidity shortages,geopolitical events or otherwise.Raising additional capital may cause dilution to our stockholders restrict our operations or require us to relinquish rights to our technologies or product candidates.Until such time,if ever,as we can generate substantial product revenue,we expect to finance our cash needs through equity offerings,debt financings,or other capital sources,including potential collaborations,licenses and other similar arrangements.We do not have any committed external source of funds.To the extent that we raise additional capital through the sale of equity or convertible debt securities,your ownership interest may be diluted,and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder.Debt financing and preferred equity financing,if available,may involve agreements that include covenants limiting or restricting our ability to take specific actions,such as incurring additional debt,making capital expenditures or declaring dividends.Such restrictions could adversely impact our ability to conduct our operations and execute our business plan.If we raise additional funds through future collaborations,licenses and other similar arrangements,we may be required to relinquish valuable rights to our future revenue streams,product candidates,research programs,intellectual property or proprietary technology,or grant licenses on terms that may not be favorable to us and / or that may reduce the value of our common stock.If we are unable to raise additional funds **through equity or debt financings or other arrangements when needed or on terms acceptable to us,we would be required to delay,limit,reduce or terminate our product development or future commercialization efforts,or grant rights to develop and market product candidates that we might otherwise prefer to develop and market ourselves,or on less favorable terms than we would otherwise choose.** Our operating results may fluctuate significantly, which makes our future operating results difficult to predict and could cause our operating results to fall below expectations or any guidance we may provide. Our quarterly and annual operating results may fluctuate significantly, which makes it difficult for us to predict our future operating results. These fluctuations may occur due to a variety of factors, many of which are outside of our control, including, but not limited to: • the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to cretostimogene or any future product candidates, which may change from time to time, including the need to conduct unanticipated clinical trials or trials that are larger or more complex than anticipated; • our ability to enroll patients in clinical trials and the timing of enrollment; • the timing and success or failure of preclinical studies or clinical trials for cretostimogene or any future product candidates or competing product candidates, or any other change in the competitive landscape of our industry, including consolidation among our competitors or partners; • coverage and reimbursement policies with respect to cretostimogene or any future product candidates, if approved, and potential future drugs that compete with our products; • the cost of manufacturing cretostimogene or any future product candidates, which may vary depending on the quantity of production and the terms of our agreements with third- party manufacturers; • expenditures that we may incur to acquire, in- license, develop, or commercialize additional product candidates; • the level of demand for any approved products, which may vary significantly and be difficult to predict; • our ability to commercialize cretostimogene or any future product candidates, if approved, inside and outside of the United States, either independently or working with third parties; • our ability to establish and maintain collaborations, licensing or other arrangements; • potential unforeseen business disruptions that increase our costs or expenses; • future accounting pronouncements or changes in our accounting policies; and • the timing and amount of any milestone, royalty or other payments payable by us or due to us under any collaboration, licensing or other similar agreement. The cumulative effects of these factors could result in large fluctuations and unpredictability in our quarterly and annual operating results. As a result, comparing our operating results on a period- to- period basis may not be meaningful. Investors should not rely on our past results as an indication of our future performance. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially. Such a stock price decline could occur even when we have met any previously publicly stated revenue or earnings guidance we may provide. Our success is dependent on our ability to attract and retain highly qualified management and other clinical and scientific personnel. Our success depends in part on our continued ability to attract, recruit, retain, manage, and motivate highly qualified management, clinical, and scientific personnel, and we face significant competition for experienced personnel. We are highly dependent upon our senior management, as well as our senior scientists and other members of our management team. The loss of services of any of these individuals could delay or prevent the successful development of our product pipeline, initiation or completion of our clinical trials and preclinical studies, regulatory approvals or the commercialization of cretostimogene or any future product candidates. Although we have executed employment agreements or offer letters with each member of our senior management team, these agreements are terminable at will with or without notice and, therefore, we may not be able to retain their services as expected. We do not currently maintain " key person " life insurance on the lives of our executives or any of our employees. This lack of insurance means that we may not have adequate compensation for the loss of the services of these individuals. In addition, employment candidates and existing employees often consider the value of the stock awards they receive in connection with their employment. If the perceived benefits of our stock awards decline, either because we are a public company or for other reasons, it may harm our ability to recruit and retain highly skilled employees. Our employees may be more likely to leave us if the shares they own have significantly appreciated in value relative to the original purchase prices of the shares, or if the exercise prices of the options that they hold are significantly below the market price of our common stock, particularly after the expiration of the lock- up agreements described herein. We will need to expand and effectively manage our managerial, operational, financial and other

resources in order to successfully pursue our clinical development and commercialization efforts. We may not be successful in maintaining our unique company culture and continuing to attract or retain qualified management, clinical, and scientific personnel in the future due to the intense competition for qualified personnel among biopharmaceutical, biotechnology and other businesses. Our industry has experienced a high rate of turnover of management personnel in recent years. If we are not able to attract, integrate, retain and motivate necessary personnel to accomplish our business objectives, we may experience constraints that will significantly impede the achievement of our development objectives, our ability to raise additional capital and our ability to implement our business strategy. We may encounter difficulties in managing our growth and expanding our operations successfully, ~~including our recent CFO transition,~~ which could disrupt our operations. As of December 31, ~~2023~~ **2024**, we had ~~61~~ **113** full- time employees. As we continue development and pursue the potential commercialization of cretostimogene or any future product candidates ~~, as well as transition to functioning as a public company~~, we will need to expand our financial, development, regulatory, manufacturing, information technology, marketing and sales capabilities or contract with third parties to provide these capabilities for us. As our operations expand, we expect that we will need to manage additional relationships with various strategic partners, suppliers and other third parties and we may not be successful in doing so. Our future financial performance and our ability to develop and commercialize cretostimogene and any future product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively ~~. In addition, in January 2024, we appointed Corleen Roche as our Chief Financial Officer succeeding Stephen DiPalma. While we expect Mr. DiPalma to continue to provide consulting services to assist with the transition on a part- time basis, we may experience difficulties associated with timely and successfully executing a smooth transition of the Chief Financial Officer functions~~. We are subject to various U. S. federal, state and foreign healthcare laws and regulations, which could increase compliance costs, and our failure to comply with these laws and regulations could harm our reputation, subject us to significant fines and liability or otherwise adversely affect our business. Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third- party payors, patient organizations and customers expose us to broadly applicable foreign, federal and state fraud and abuse and other healthcare laws and regulations. These laws may constrain the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell and distribute any products for which we obtain regulatory approval. Such laws include: • the federal Anti- Kickback Statute, which prohibits, among other things, persons or entities from knowingly and willfully soliciting, offering, receiving or providing any remuneration (including any kickback, bribe or certain rebates), directly or indirectly, overtly or covertly, in cash or in kind, in return for, either the referral of an individual or the purchase, lease, or order, or arranging for or recommending the purchase, lease, or order of any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the federal Anti- Kickback Statute or specific intent to violate it in order to have committed a violation; • the federal false claims laws, including the civil False Claims Act, and civil monetary penalties laws, 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, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or from knowingly making or causing to be made 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 civil False Claims Act; • the federal Health Insurance Portability and Accountability Act of 1996 (HIPAA), which imposes criminal and civil liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement, in connection with the delivery of, or payment for, healthcare benefits, items or services. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; • the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children' s Health Insurance Program (with certain exceptions) to report annually to the ~~Centers for Medicare & Medicaid Services (~~CMS ~~)~~, information related to payments and other " transfers of value " made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non- physician practitioners (physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiology assistants and certified nurse- midwives), and teaching hospitals and other healthcare providers, as well as ownership and investment interests held by physicians and their immediate family members; and • analogous state and foreign laws and regulations, such as state anti- kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third- party payors, including private insurers; some state laws require biopharmaceutical companies to comply with the biopharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government and may require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures; some state laws that require biopharmaceutical companies to report information on the pricing of certain drug products; and some state and local laws that require the registration or pharmaceutical sales representatives. Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare and privacy laws and regulations will involve ongoing substantial costs. It is possible that governmental authorities will conclude that our business practices, including certain consulting agreements and advisory board agreements we have entered into with physicians who are paid, in part, in the form of stock or stock options, may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices

might be challenged under one or more of these 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 civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government- funded healthcare programs, such as Medicare and Medicaid, integrity oversight and reporting obligations, contractual damages, reputational harm, diminished profits and future earnings and the curtailment or restructuring of our operations. Defending against any such actions can be costly and time- consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business are found not to be in compliance with applicable laws or regulations, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government- funded healthcare programs. Current and future healthcare reform legislation or regulation may increase the difficulty and cost for us to obtain coverage for and commercialize cretostimogene or any future product candidates and may adversely affect the prices we may set. In the United States and some foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system, including cost- containment measures that may reduce or limit coverage and reimbursement for newly approved drugs and affect our ability to profitably sell cretostimogene or any future product candidates for which we obtain regulatory approval. In particular, there have been and continue to be a number of initiatives at the U. S. federal and state levels that seek to reduce healthcare costs and improve the quality of healthcare. For example, in March 2010, the **ACA** ~~Patient Protection and Affordable Care Act~~ , as amended by the Health Care and Education Reconciliation Act of 2010 ~~(ACA)~~ was enacted in the United States ~~. The ACA established~~ **, which substantially changed healthcare financing, access** ~~an~~ **and** ~~annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic agents; extended manufacturers' Medicaid rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; expanded eligibility criteria for Medicaid programs; expanded the entities eligible for discounts under the 340B drug pricing program; increased the statutory minimum rebates a manufacturer must pay under the Medicaid Drug Rebate Program; established a new Patient- Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research, along with funding for such research; and established a Center for Medicare & Medicaid Innovation at CMS to test innovative payment and service~~ delivery **by both governmental** ~~models to lower Medicare~~ and ~~Medicaid spending~~ **private insurers** . Since its enactment, there have been executive, judicial and Congressional challenges **and amendments** to certain aspects of the ACA. ~~On June 17, 2021, the U. S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. In addition, other legislative changes have been proposed and adopted since the ACA was enacted.~~ For example, ~~beginning April 1, 2013, Medicare payments to providers were reduced under the sequestration required by the Budget Control Act of 2011, which will remain in effect until 2032, unless additional Congressional action is taken. Additionally,~~ on ~~January 2~~ **August 16** , ~~2013, the American Taxpayer Relief Act of 2012~~ , **2022 , the IRA** was signed into law ~~, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. On March 11, 2021, the American Rescue Plan Act of 2021 was signed into law, which eliminates the statutory cap on the Medicaid drug rebate, beginning January 1, 2024. The rebate was previously capped at 100 % of a drug' s average manufacturer price. Further, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices in light of the rising cost of prescription drugs. Such scrutiny has resulted in several recent congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient assistance programs, and reform government program reimbursement methodologies for products. Most recently, on August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 (IRA) into law. This statute marks the most significant action by Congress with respect to the pharmaceutical industry since adoption of the ACA in 2010~~ . Among other things, the IRA (i) directs HHS to negotiate the price of certain high- expenditure, single- source ~~drugs and~~ biologics **that have been on the market for at least 11 years** covered under Medicare **(the " Medicare Drug Price Negotiation Program ")** and (ii) imposes rebates under Medicare Part B and Medicare Part D to penalize price increases that outpace inflation. The IRA permits the Secretary of the ~~Department of Health and Human Services (~~HHS ~~)~~ to implement many of these provisions through guidance, as opposed to regulation, for the initial years. HHS has and will continue to issue and update guidance as these programs are implemented. On August ~~29~~ **15** , ~~2023~~ **2024** , HHS announced the ~~list~~ **agreed- upon price** of the first ten drugs that **were** ~~will be~~ subject to price negotiations, although the Medicare ~~drug~~ **Drug** ~~price~~ **Price** ~~negotiation~~ **Negotiation** ~~program~~ **Program** is currently subject to legal challenges. **On January 17, 2025, HHS selected fifteen additional products covered under Part D for price negotiation in 2025. Each year thereafter more Part B and Part D products will become subject to the Medicare Drug Price Negotiation Program.** The **current Trump administration is pursuing policies to reduce regulations and expenditures across government including at HHS, the FDA, the CMS and related agencies. These actions, presently directed by executive orders or memoranda from the Office of Management and Budget, may propose policy changes that create additional uncertainty for our business. These actions may, for example, include directives to reduce agency workforce, rescinding a Biden administration executive order tasking the CMMI to consider new payment and healthcare models to limit drug spending and eliminating the Biden administration' s executive order that directed HHS to establishing an AI task force and developing a strategic plan. Additionally, in its June 2024 decision in Loper Bright, the U. S. Supreme Court overturned the longstanding Chevron doctrine, under which courts were required to give deference to regulatory agencies' reasonable interpretations of ambiguous federal statutes. The Loper Bright decision could result in additional legal challenges to current regulations and guidance issued by federal agencies applicable to our operations, including those**

issued by the FDA. Congress may introduce and ultimately pass health care related legislation that could impact ~~of~~ **the drug approval process and make changes to the Medicare Drug Price Negotiation Program created under** the IRA ~~on the pharmaceutical industry cannot yet be fully determined but is likely to be significant. Additional drug pricing proposals could appear in future legislation~~ . At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Legally mandated price controls on payment amounts by third- party payors or other restrictions could harm our business, financial condition, results of operations and prospects. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. This could reduce the ultimate demand for cretostimogene and any future product candidates, if approved, or put pressure on our product pricing, which could negatively affect our business, financial condition, results of operations and prospects. We expect that these existing laws and other healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, new payment methodologies and additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize cretostimogene or any future product candidates, if approved. If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit, delay or cease commercialization of our products. We face an inherent risk of product liability as a result of the clinical trials of cretostimogene and any future product candidates and will face an even greater risk if we commercialize cretostimogene or any future product candidates, if approved. For example, we may be sued if cretostimogene or any future product candidates allegedly cause injury or are found to be otherwise unsuitable during product testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product candidate, negligence, strict liability and a breach of warranties. Claims may be brought against us by clinical trial participants, patients or others using, administering or selling products that may be approved in the future. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit, delay or cease the commercialization of our products. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in: • decreased demand for our products; • injury to our reputation and significant negative media attention; • withdrawal of clinical trial participants; • costs to defend the related litigation; • a diversion of our management' s time and our resources; • substantial monetary awards to trial participants or product recipients; • product recalls, withdrawals or labeling, marketing or promotional restrictions; • significant negative financial impact; • the inability to commercialize cretostimogene or any future product candidate; and • a decline in our stock price. We currently hold approximately $ 10 million in product liability insurance coverage in the aggregate. We may need to increase our insurance coverage as we expand our clinical trials or if we commence commercialization of cretostimogene or any future product candidates. Insurance coverage is increasingly expensive. Our inability to obtain and retain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of cretostimogene or any future product candidates. Although we will maintain such insurance, any claim that may be brought against us could result in a court judgment or settlement in an amount that is not covered, in whole or in part, by our insurance or that is in excess of the limits of our insurance coverage. Our insurance policies will also have various exclusions, and we may be subject to a product liability claim for which we have no coverage. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts. Our insurance policies are expensive and protect us from only 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 property, general liability, employee benefits liability, business automobile, workers' compensation, products / clinical trial liability, cyber liability, clinical trials, directors' and officers' and employment practices insurance. We do not know, however, if we will be able to maintain insurance with adequate levels of coverage. No assurance can be given that an insurance carrier will not seek to cancel or deny coverage after a claim has occurred. Any significant uninsured liability may require us to pay substantial amounts, which would adversely affect our business, financial condition, results of operations and prospects. We and any of our current or potential future collaborators will be required to report to regulatory authorities if any of our approved products cause or contribute to adverse medical events, and any failure to do so would result in sanctions that would materially harm our business. If we or any of our current or potential future collaborators are successful in commercializing cretostimogene or any future product candidates, the FDA and foreign regulatory authorities would require that we and such collaborators report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we or such collaborators become aware of the adverse event as well as the nature of the event. We and any of our current or potential future collaborators or CROs may fail to report adverse events within the prescribed timeframe. If we or any of our current or potential future collaborators or CROs fail to comply with such reporting obligations, the FDA or a foreign regulatory authority could take action, including criminal prosecution, the imposition of civil monetary penalties, seizure of our products or delay in approval or clearance of future products. We and our service providers **are** ~~may be~~ subject to a variety of **stringent and evolving U. S. and foreign** data protection, privacy and security obligations, including laws, regulations, standards and contractual provisions, which could increase compliance costs, and ~~our~~ **any** actual or perceived failure **by us or our service providers** to

comply with such laws and obligations could subject us to potentially significant liability, fines or penalties and otherwise harm our business. We and our service providers maintain and will maintain a large quantity of sensitive information **. In the ordinary course of business** , ~~including~~ **we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, process)** confidential business and patient health information, **personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants** in connection with ~~our~~ clinical trials **, sensitive third-party data, business plans, transactions, financial information** , and are subject to laws and regulations governing the privacy and security of such information. The global data protection landscape is rapidly evolving, and we and our service providers **are and** may be affected by or subject to existing, amended, or new laws and regulations in the future, including as our operations continue to expand or if we operate in foreign jurisdictions. These laws and regulations may be subject to differing interpretations, thus creating potentially complex compliance issues for us and our service providers, strategic partners and future customers. The cost of compliance with these laws, regulations and standards is high and is likely to increase in the future. Any failure or perceived failure by us to comply with federal, state or foreign laws or regulations, our internal policies and procedures or our contracts governing our processing of personal information could result in negative publicity, government investigations and enforcement actions, claims by third parties and damage to our reputation, any of which could have a material adverse effect on our business, financial condition, results of operations and prospects. As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, numerous federal and state laws and regulations, including health information privacy laws, data breach notification laws and consumer protection laws, that govern the collection, use, storage, transfer, disclosure, protection and other processing of health- related and other personal information could apply to our operations or the operations of our collaborators and third- party providers. In addition, we ~~may~~ obtain health information from third parties (including research institutions from which we obtain clinical trial data and CROs) that are subject to privacy and security requirements under HIPAA. Consequently, depending on the facts and circumstances, we could be subject to significant penalties if we knowingly receive individually identifiable health information from a HIPAA- covered healthcare provider, research institution, or CRO that has not satisfied HIPAA' s requirements for disclosure of individually identifiable health information. In addition, certain state laws govern the privacy and security of health- related and other personal information, many of which may differ from each other and from HIPAA, thus complicating compliance efforts. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and / or criminal penalties and private litigation. By way of example, the California Consumer Privacy Act (CCPA), which went into effect on January 1, 2020, gives California residents a number of individual privacy rights related to how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that has increased the likelihood of, and risks associated with data breach litigation. Further, the California Privacy Rights Act (CPRA) generally went into effect on January 1, 2023. The CPRA imposes additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also creates a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional compliance investment and potential business process changes may be required. Similar laws have been passed in other states, and are continuing to be proposed at the state and federal level, reflecting a trend toward more stringent privacy legislation in the United States. In the event that we are subject to or affected by HIPAA, the CCPA, the CPRA or other domestic privacy and data protection laws, any liability from failure to comply with the requirements of these laws could adversely affect our financial condition. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, store, use, transfer, disclose and otherwise process data, update our data privacy and security policies and procedures, or in some cases, impact our ability to operate in certain jurisdictions. Failure by us or our collaborators and our service providers to comply with U. S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and / or adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, ~~may~~ **often** contractually limit our ability to use and disclose such information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time consuming to defend, could result in adverse publicity and adversely affect our business, financial condition, results of operations and prospects. ~~Our~~ **If our** information technology systems ~~,~~ or those ~~of any of~~ **third parties with whom we work** ~~our~~ **or** ~~service providers, may fail or~~ **our data** ~~suffer security incidents and other disruptions~~ , ~~which~~ **are or were compromised, we** could **experience adverse consequences** ~~result~~ **resulting** ~~in a~~ **from such compromise, including but not limited to** material disruption of our development programs, compromise **of** sensitive information related to our business **, inability to** ~~or prevent us from accessing~~ **access** critical information, potentially exposing us to liability or otherwise adversely affecting our business. In the ordinary course of business, we collect, store and transmit confidential information (including but not limited to intellectual property, proprietary and confidential business information and personal information). Our information technology systems and those of our third- party service providers, strategic partners and other contractors or consultants are vulnerable to attack, damage and interruption from computer viruses and malware (e. g. ransomware), malicious code, natural disasters, terrorism, war, telecommunication and electrical failures, hacking, cyberattacks, phishing attacks and other social engineering schemes, employee theft or misuse, human error, fraud, denial or degradation of service attacks, sophisticated nation- state and nation-state- supported actors or unauthorized access or use by persons inside our organization, or persons with access to systems inside our organization. In addition, attacks upon information technology systems are increasing in their frequency, levels of

persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Furthermore, because the techniques used to obtain unauthorized access to, or to sabotage, systems change frequently and often are not recognized until launched against a target, we ~~may~~ **could** be unable to anticipate these techniques or implement adequate preventative measures. ~~We may also experience~~ **Remote work has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers and devices outside our premises or network, including working at home, while in transit and in public locations.** ~~security~~ **Security** incidents **often** ~~that may~~ remain undetected for an extended period **and could affect our operations** . Even if identified, we may be unable to adequately investigate or remediate incidents or breaches due to attackers increasingly using tools and techniques that are designed to circumvent controls, to avoid detection, and to remove or obfuscate forensic evidence. We and certain of our service providers are from time to time subject to cyberattacks and security incidents. While we do not believe that we have experienced any material system failure, accident or security breach to date, if any such event, whether actual or perceived, were to occur, it could impact our reputation and / or operations, cause us to incur significant costs, including legal expenses, harm customer confidence, hurt our expansion into new markets, cause us to incur remediation costs, or cause us to lose existing customers. For example, the loss of clinical trial data from clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. We also rely on a third party to manufacture cretostimogene, and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any actual or perceived disruption or security incident affects our systems (or those of our third-party collaborators, service providers, contractors or consultants) or were to result in a loss of or accidental, unlawful or unauthorized access to, use of, release of, or other processing of personally identifiable information, or damage to, our confidential or proprietary data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability, the further development and commercialization of cretostimogene or any future product candidates could be delayed, and we could be subject to significant fines, penalties or liabilities for any noncompliance to certain privacy and security laws. We have also outsourced elements of our information technology infrastructure, and as a result a number of third-party vendors ~~may~~ **have** or could have access to our confidential information. If our third- party vendors fail to protect their information technology systems and our confidential and proprietary information, we may be vulnerable to disruptions in service and unauthorized access to our confidential or proprietary information and we could incur liability and reputational damage. If the information technology systems of our third- party vendors and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Some of the federal, state and foreign government requirements include obligations of companies to notify individuals of security breaches involving particular categories of personally identifiable information, which could result from incidents experienced by us or by our vendors, contractors, or organizations with which we have formed strategic relationships. Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. Although we currently hold cybersecurity insurance, the costs related to significant security breaches or disruptions could be material and cause us to incur significant expenses. Our business is subject to risks arising from pandemics and epidemic diseases. The COVID- 19 worldwide pandemic presented substantial public health and economic challenges and affected our employees, patients, physicians and other healthcare providers, communities and business operations, as well as the U. S. and global economies and financial markets. Any future pandemic or epidemic disease outbreaks could disrupt the supply chain and the manufacture or shipment of drug substances and finished drug products for cretostimogene or any future product candidates for use in our, our collaborators' or any future collaborators' clinical trials and research and preclinical studies and, delay, limit or prevent our employees and CROs from continuing research and development activities, impede our clinical trial initiation and recruitment and the ability of patients to continue in clinical trials, alter the results of the clinical trial based on participants contracting the disease or otherwise increasing the number of observed adverse events, impede testing, monitoring, data collection and analysis and other related activities, any of which could delay our preclinical studies and clinical trials and increase our development costs, and have a material adverse effect on our business, financial condition, results of operations and prospects. Any future pandemic or epidemic disease outbreak could also potentially further affect the business of the FDA, European Medicines Agency or other regulatory authorities, which could result in delays in meetings related to our planned clinical trials, as well have an adverse impact on global economic conditions which could have an adverse effect on our business and financial condition, including impairing our ability to raise capital when needed. Our business could be affected by litigation, government investigations and enforcement actions. We currently operate in a number of jurisdictions in a highly regulated industry and we could be subject to litigation, government investigation and enforcement actions on a variety of matters in the United States or foreign jurisdictions, including, without limitation, intellectual property, regulatory, product liability, environmental, whistleblower, false claims, privacy, anti- kickback, anti- bribery, securities, commercial, employment and other claims and legal proceedings that may arise from conducting our business. Any determination that our operations or activities are not in compliance with existing laws or regulations could result in the imposition of fines, civil and criminal penalties, equitable remedies, including disgorgement, injunctive relief and / or other sanctions against us, and remediation of any such findings could have an adverse effect on our business operations. Legal proceedings, government investigations and enforcement actions can be expensive and time- consuming. For example, on March 4, 2024, a complaint was filed in the Superior Court of the State of Delaware by ANI Pharmaceuticals, Inc. **(ANI)** naming us as defendant, seeking a declaratory judgement that a provision in an assignment and technology transfer agreement between us and ANI (formerly BioSante Pharmaceuticals, Inc.), dated November 15, 2010, obligates us to pay ANI 5 % of worldwide net sales of cretostimogene. **The court has most recently set a trial date of July 21, 2025.** While we **continue to** believe the allegations are without merit and

intend to vigorously defend this matter, such litigation could result in substantial costs and divert our management' s attention from other business concerns, cause us reputational damage, negatively affect our stock price and result in monetary damages and future royalty obligations, if and to the extent cretostimogene receives regulatory approval. An adverse outcome resulting from any legal proceedings, investigations or enforcement actions could result in significant damages awards, fines, penalties, exclusion from the federal healthcare programs, healthcare debarment, injunctive relief, product recalls, reputational damage and modifications of our business practices, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Even if such a proceeding, investigation or enforcement action is ultimately decided in our favor, the investigation and defense thereof could require substantial financial and management resources. Our employees and independent contractors, including collaborators, principal investigators, CROs, consultants and vendors, may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk that our employees and independent contractors, including collaborators, principal investigators, CROs, consultants, and vendors may engage in misconduct or other illegal activity. Misconduct by these parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities to us that violate: (i) the laws and regulations of the FDA and other similar regulatory requirements, including those laws that require the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, including cGMP requirements, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad (iv) laws that require the true, complete and accurate reporting of financial information or data, or (v) laws that prohibit insider trading. Activities subject to these laws also involve the improper use or misrepresentation of information obtained in the course of clinical trials, the creation of fraudulent data in our or our collaborators' preclinical studies or clinical trials, or illegal misappropriation of drug product, which could result in regulatory sanctions and cause serious harm to our reputation. It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. In addition, we are subject to the risk that a person or government could allege such fraud or other misconduct, even if none occurred. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business and financial results, including, without limitation, the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgements, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non- compliance with these laws and curtailment of our operations, any of which could adversely affect our business, financial condition, results of operations and prospects. We may engage in strategic transactions that could impact our liquidity, increase our expenses, and present significant distractions to our management. From time to time, we may consider strategic transactions, such as acquisitions of companies, asset purchases, and out- licensing or in- licensing of intellectual property, products or technologies. Additional potential transactions that we may consider in the future include a variety of business arrangements, including spin- offs, strategic partnerships and collaborations, joint ventures, restructurings, divestitures, business combinations, and investments. We may not be able to find suitable partners or acquisition candidates, and we may not be able to complete such transactions on favorable terms, if at all. Any future transactions could increase our near and long- term expenditures, result in potentially dilutive issuances of our equity securities, including our common stock, or the incurrence of debt, contingent liabilities, amortization expenses or acquired in- process research and development expenses, any of which could affect our financial condition, liquidity and results of operations. Future acquisitions may also require us to obtain additional financing, which may not be available on favorable terms or at all. These transactions may never be successful and may require significant time and attention of our management. In addition, the integration of any business that we may acquire in the future may disrupt our existing business and may be a complex, risky and costly endeavor for which we may never realize the full benefits. Furthermore, we may experience losses related to investments in other companies, including as a result of failure to realize expected benefits or the materialization of unexpected liabilities or risks, which could have a material negative effect on our results of operations and financial condition. Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, financial condition, results of operations and prospects. Our ability to use net operating loss carryforwards and other tax attributes may be limited. We have incurred substantial losses during our history, do not expect to become profitable in the near future and may never achieve profitability. As of December 31, ~~2023~~ **2024**, we had net operating loss (NOL) carryforwards, which may be available to offset our future taxable income, if any. Our NOL carryforwards and other tax attributes are subject to expiration, review and possible adjustment by the Internal Revenue Service (IRS) and state tax authorities **. Under current law, NOLs incurred in taxable years beginning after December 31, 2017, can be carried forward indefinitely, but the deductibility of such U. S. federal NOLs in a taxable year is limited to 80 % of taxable income in such year**. In addition, under Section 382 of the U. S. Internal Revenue Code of 1986, as amended (the Code), our federal NOL carryforwards may be or become subject to an annual limitation in the event we have had or have in the future an " ownership change. " For these purposes, an " ownership change " generally occurs if one or more stockholders or groups of stockholders who own at least 5 % of a company' s stock increase their ownership by more than 50 percentage points over their lowest ownership percentage within a rolling three- year period. Similar rules may apply under state tax laws. Although we believe there have been one or more ownership changes resulting from past transactions, we have not determined the amount of the cumulative change in our ownership resulting from our initial public offering or other transactions, or any resulting limitations on our ability to utilize our NOL carryforwards and other tax attributes. However, we believe that our ability to utilize our NOL carryforwards and other tax attributes to offset future taxable

income or tax liabilities may be limited as a result of ownership changes. **In addition** ~~If we earn taxable income~~ , **at the state level, there may be periods during which the use of NOLs is suspended or otherwise limited, which could accelerate or permanently increase state taxes owed. For example, California recently imposed limits on the usability of California state NOL carryforwards and certain state tax credits in tax years beginning after 2023 and before 2027.** ~~such~~ **Such** limitations could result in increased future income tax liability to us and our future cash flows could be adversely affected. We have recorded a full valuation allowance related to our NOL carryforwards and other deferred tax assets due to the uncertainty of the ultimate realization of the future benefits of those assets. ~~Risks Related to Our Intellectual Property~~ If we are unable to obtain, maintain, defend and enforce patent or other intellectual property protection for cretostimogene or any future product candidates or technology, or if the scope of the patent or other intellectual property protection obtained is not sufficiently broad, our competitors or other third parties could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize cretostimogene or any future product candidates may be adversely affected. We rely, and may in the future rely, upon a combination of patent, trade secrets and trademark protection for cretostimogene and any future product candidates and proprietary technologies to prevent third parties from exploiting our achievements, thus eroding our competitive position in our market. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and proprietary information. Our success depends in large part on our ability to obtain, maintain, expand, enforce, and defend the scope, ownership or control, validity and enforceability of our intellectual property protection in the United States and other countries with respect to cretostimogene and any future product candidates and other proprietary technologies we may develop. We generally seek, and may in the future seek, to protect our proprietary position, in part, by filing patent applications in the United States and abroad relating to cretostimogene and any future product candidates and technology, manufacturing processes and methods of use. We may also seek to protect our proprietary position by acquiring or in- licensing relevant issued patents or pending patent applications from third parties. Currently **,** we do not have composition of matter patents covering cretostimogene. We will endeavor to seek additional patent protection to cover features of the oncolytic virus and formulations in the future. If we are unable to obtain, maintain, expand, enforce and defend the scope, ownership or control, validity and enforceability of our intellectual property protection, our business, financial condition, results of operations and prospects could be materially harmed. Changes in either the patent laws or their interpretation in the United States and other jurisdictions may diminish our ability to protect our intellectual property, obtain, maintain, expand, enforce and defend our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our protection. We cannot predict whether the patent applications we currently or may in the future pursue or may in- license will issue as patents in any particular jurisdiction, whether the claims of any issued patents will provide sufficient protection against competitors or other third parties, or if these patents are challenged by our competitors, whether the patents will be found to be invalid, unenforceable, or not infringed or not owned or controlled by us. The patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, defend or license all necessary or desirable patent applications or patents at a reasonable cost or in a timely manner or in all jurisdictions. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non- disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, licensees, third- party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. Consequently, we may not be able to prevent any third party from using any of our technology that is in the public domain to compete with cretostimogene or any future product candidates or technologies. 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 in light of the prior art. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we or the entity from which we purchased the intellectual property rights to cretostimogene were the first to invent the inventions claimed in any of our owned patents or pending patent applications, or that we or any future licensors were the first to file for patent protection of such other inventions. If a third party can establish that we were not the first to make or the first to file for patent protection of such other inventions, our patents and patent applications may not issue as patents and even if issued, may be challenged and invalidated or rendered unenforceable. The patent position of biopharmaceutical companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain. Our current and future patent applications may not result in patents being issued. Any issued patents may not afford sufficient protection of cretostimogene or any future product candidates or their intended uses against competitors, nor can there be any assurance that the issued patents will not be infringed, designed around, invalidated by third parties, or effectively prevent others from commercializing competitive technologies, products or cretostimogene or any future product candidates. Further, even if these patents are granted, they may be difficult to enforce. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, information disclosure, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we fail to comply with these requirements. In the event we experience noncompliance events that cannot be corrected and we lose our patent rights, competitors could enter the market, which would have a material adverse effect on our business. Further, any issued patents that we own or may license in the future covering cretostimogene or any future product candidates could be narrowed or found invalid or unenforceable if challenged in court or before administrative bodies in the United States or other countries, including the U. S. Patent and Trademark Office (USPTO). Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-

enablement. In addition, patent validity challenges may, under certain circumstances, be based upon non- statutory obviousness-type double patenting, which, if successful, could result in a finding that the claims are invalid for obviousness- type double patenting or the loss of patent term, including a patent term adjustment granted by the USPTO. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld information material to patentability from the USPTO, or made a misleading statement, during prosecution. Also, patent terms, including any extensions or adjustments that may or may not be available to us, may be inadequate to protect our competitive position on cretostimogene or any future product candidates for an adequate amount of time, and we may be subject to claims challenging the inventorship, ownership, validity, enforceability of our patents and / or other intellectual property. Changes in U. S. patent law, or laws in other countries, could diminish the value of patents in general, thereby impairing our ability to protect cretostimogene or any future product candidates. Further, if we encounter delays in our development and testing of cretostimogene or any future product candidates, clinical trials or regulatory review and approval of cretostimogene or any future product candidates, the period of time during which we could market cretostimogene or any future product candidates under patent protection may be reduced (i. e., patents protecting such product candidates might expire before or shortly after such product candidates are commercialized). Thus, our patents may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or afford us any meaningful competitive advantage. Moreover, the claim coverage in a patent application can be significantly reduced before the corresponding patent is granted. Even if patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us or otherwise provide us with any competitive advantage. Any patents issuing from our owned and any future in- licensed patent applications may be challenged, narrowed, circumvented or invalidated by third parties. Consequently, we do not know whether cretostimogene or any future product candidates and other proprietary technology will be protectable or remain protected by valid and enforceable patents. Even if a patent is granted, our competitors or other third parties may be able to circumvent the patent by developing similar or alternative technologies or products in a non- infringing manner which could materially adversely affect our business, financial condition, results of operations and prospects. Furthermore, our competitors or other third parties may avail themselves of safe harbors under the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch- Waxman Amendments) to conduct research and clinical trials. The issuance of a patent is not conclusive as to its inventorship, ownership, scope, validity, or enforceability and our patent rights may be challenged in the courts or patent offices in the United States and abroad. We may be subject to a post-grant proceeding at the USPTO challenging the validity of one or more claims of our patents or patents we may license in the future. Third- party submissions may also be made prior to a patent' s issuance, precluding the granting of a patent based on our pending patent application or patent application we may license in the future. A third party may also claim that our patent rights are invalid or unenforceable in a litigation. The outcome following legal assertions of invalidity and unenforceability is unpredictable. In addition, we may become involved in opposition, derivation, revocation, reexamination, reissue, interference proceedings or other similar proceedings in the United States and / or foreign jurisdictions challenging our patent rights. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate or render unenforceable, our patent rights, and may allow third parties, including generic drug companies, to commercialize cretostimogene or any future product candidates and other proprietary technologies we may develop and compete directly with us. Moreover, some of our patent rights may in the future be co- owned with third parties. In the United States, each co- owner has the freedom to license and exploit the technology. If we are unable to obtain an exclusive license to any such third- party co-owners' interest in such patent rights, such co- owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of such patent rights in order to enforce such patent rights against third parties, and such cooperation may not be provided to us. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, results of operations and prospects. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting, maintaining, enforcing and defending patents on cretostimogene or any future product candidates in all countries throughout the world is expensive, and the laws of foreign countries may not protect our intellectual property rights to the same extent as the laws of the United States. Prosecution of foreign patent applications is often a longer process and patents may grant at a later date, and with a shorter term, than in the United States. The requirements for patentability differ in certain jurisdictions and countries. Additionally, the patent laws of some countries do not afford intellectual property protection to the same extent as the laws of the United States. For example, other countries may impose substantial restrictions on the scope of claims, including limiting patent protection to specifically disclosed embodiments. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our intellectual property in and into the United States or other jurisdictions. Competitors may use our intellectual property in jurisdictions where we have not pursued and obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States. These products may compete with our products, and our patents or patents we may license in the future or other intellectual property rights may not be effective or sufficient to prevent them from competing. 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 biopharmaceutical products, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our intellectual property and proprietary rights generally. In addition, some jurisdictions, such as Europe, Japan and China, may have a heightened standard for patentability than in the United States, including, for example, the requirement of claims having literal support in the original patent filing and the limitation on using supporting data that is

not in the original patent filing. Under those heightened patentability requirements, we may not be able to obtain sufficient patent protection in certain jurisdictions even though the same or similar patent protection can be secured in the United States and other jurisdictions. Proceedings to enforce our intellectual property and proprietary rights in the United States or other jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and any patents we may license in the future at risk of being invalidated or interpreted narrowly, could put our patent applications and any patent applications we may license in the future at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property and proprietary rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties, including governmental agencies. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired, and our business, financial condition, results of operations and prospects may be adversely affected. In addition, geo- political actions in the United States and in foreign countries (such as the Russia and Ukraine conflict) could increase the uncertainties and costs surrounding the prosecution or maintenance of our patent applications or those of any future licensors and the maintenance, enforcement or defense of our issued patents which could impair our competitive intellectual property position. Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by government patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The USPTO and various non- U. S. government agencies require compliance with several procedural, documentary, fee payment and other similar provisions during the patent application process. In some circumstances, we may be dependent on any future licensors to take the necessary action to comply with these requirements with respect to any licensed intellectual property. For example, periodic maintenance fees, renewal fees, annuity fees, and various other government fees on patents and applications will be due to be paid to the USPTO and various government patent agencies outside of the United States over the lifetime of our patents and applications. In certain circumstances, we may rely on licensing partners to pay these fees due to the U. S. and non- U. S. patent agencies. In some cases, an inadvertent lapse can be cured by payment of a late fee or by other means in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment or lapse of the patent or patent application, resulting in a partial or complete loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the market with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. The USPTO and various non- U. S. government agencies require compliance with certain foreign filing requirements during the patent application process. For example, in some countries, including the United States, China, India and some European countries, a foreign filing license is required before certain patent applications are filed. The foreign filing license requirements vary by country and depend on various factors, including where the inventive activity occurred, citizenship status of the inventors, the residency of the inventors and the invention owner, the place of business for the invention owner and the nature of the subject matter to be disclosed (e. g., items related to national security or national defense). In some, but not all cases, for example in China and India, a foreign filing license cannot be obtained retroactively in accordance with the applicable rules. There are situations, however, in which non- compliance can result in abandonment of a pending patent application or can be grounds for revoking or invalidating an issued patent, resulting in the loss of patent rights in the relevant jurisdiction. In such an event, potential competitors might be able to enter the relevant markets with similar or identical products or technology, which could have a material adverse effect on our business, financial condition, results of operations and prospects. We would also be dependent on any future licensors to take the necessary actions to comply with these requirements with respect to any intellectual property we may license in the future. Public health pandemics (such as the COVID- 19 pandemic), geopolitical instability (war and terrorism), natural disasters, or similar events may impair our and our licensors' ability to comply with these procedural, document submission, fee payment, and other requirements imposed by government patent agencies, which may materially and adversely affect our ability to obtain or maintain patent protection for cretostimogene and any future product candidates. Changes in patent laws or their interpretations could diminish the value of patents in general, thereby impairing our ability to protect our products. Changes in either the patent laws or interpretation of the patent laws in the United States or in other countries could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of issued patents. Assuming that other requirements for patentability are met, prior to March 2013, in the United States, the first to invent the claimed invention was entitled to the patent, while outside the United States, the first to file a patent application was entitled to the patent. After March 2013, under the Leahy- Smith America Invents Act (the America Invents Act) enacted in September 2011, the United States transitioned to a first inventor to file system in which, assuming that other requirements for patentability are met, the first inventor to file a patent application will be entitled to the patent on an invention regardless of whether a third party was the first to invent the claimed invention. A third party that files a patent application in the USPTO after March 2013, but before us or our licensors could therefore be awarded a patent covering an invention of ours or our licensors even if we or our licensors had made the invention before it was made by such third party. This requires us to be cognizant of the time from invention to filing of a patent application. Since patent applications in the United States and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we or our licensors are the first to either (i) file any patent application related to cretostimogene or any future product candidates and other proprietary technologies we may develop or (ii) invent any of the inventions claimed in our patents or patent applications. The America Invents Act also included a number of significant changes that affect the way patent applications are prosecuted and also affect patent litigation.

These include allowing third party protests and submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO- administered post- grant proceedings, including post- grant review, inter partes review and derivation proceedings. 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. Accordingly, a third party may attempt to use the USPTO procedures to invalidate our patent claims or any patent claims we may license in the future that would not have been invalidated if first challenged by the third party as a defendant in a district court action. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Recent U. S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances and weakened the rights of patent owners in certain situations. We cannot predict how decisions by the courts, the U. S. Congress or the USPTO may impact the value of our patent rights. For example, the U. S. Supreme Court held in Amgen v. Sanofi (2023) that a functionally claimed genus was invalid for failing to comply with the enablement requirement of the Patent Act. As such, our patent rights with functional claims may be vulnerable to third party challenges seeking to invalidate these claims for lacking enablement or adequate support in the specification. Depending on future actions by the U. S. Congress, the federal courts and the USPTO, the laws and regulations governing patents could change in unpredictable ways that could have a material adverse effect on our existing patent portfolio and our ability to protect and enforce our intellectual property in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions or changes in the governmental bodies that enforce them or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have or may obtain or license in the future. In 2012, the European Union Patent Package (EU Patent Package) regulations were passed with the goal of providing a single pan- European Unitary Patent and a new European Unified Patent Court (UPC) for litigation involving European patents. The EU Patent Package was implemented on June 1, 2023. As a result, all European patents, including those issued prior to ratification of the EU Patent Package, now by default automatically fall under the jurisdiction of the UPC, unless otherwise opted out. It is uncertain how the UPC will impact granted European patents in the biotechnology and pharmaceutical industries. Our European patent applications, if issued, could be challenged in the UPC. During the first seven years of the UPC' s existence, the UPC legislation allows a patent owner to opt its European patents out of the jurisdiction of the UPC. We may decide to opt out our future European patents from the UPC, but doing so may preclude us from realizing the benefits of the UPC. Moreover, if we do not meet all of the formalities and requirements for opt- out under the UPC, our future European patents could remain under the jurisdiction of the UPC. The UPC will provide our competitors with a new forum to centrally revoke our European patents, and allow for the possibility of a competitor to obtain pan- European injunction. Such a loss of patent protection could have a material adverse impact on our business and our ability to commercialize our technology and cretostimogene and any future product candidates due to increased competition and, resultantly, on our business, financial condition, results of operations and prospects. The UPC and Unitary Patent are significant changes in European patent practice. As the UPC is a new court system, there is no precedent for the court, increasing the uncertainty of any litigation in the UPC. Issued patents covering cretostimogene or any future product candidates could be found invalid or unenforceable if challenged in court or before administrative bodies in the United States or abroad. Our patent rights may be subject to priority, validity, inventorship, ownership and enforceability disputes. Legal proceedings relating to intellectual property claims, with or without merit, are unpredictable and generally expensive and time- consuming and likely to divert significant resources from our core business, including distracting our management and scientific personnel from their normal responsibilities and generally harm our business. If we or any future licensors are unsuccessful in any of these proceedings, such patents and patent applications may be narrowed, invalidated or held unenforceable. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. If we initiate legal proceedings against a third party to enforce a patent covering cretostimogene or any future product candidates, the defendant could counterclaim that such patent is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could include an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, non- enablement, lack of sufficient written description, failure to claim patent- eligible subject matter or obviousness- type double patenting. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading or inconsistent statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of a patent before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re- examination, post- grant review, inter partes review, interference proceedings, derivation proceedings, and equivalent proceedings in foreign jurisdictions (e. g., opposition proceedings). Such proceedings could result in the revocation of, cancellation of, shortening the term of or amendment to our patent rights or any patent rights we may obtain or license in the future in such a way that they no longer cover cretostimogene or any future product candidates or prevent third parties from competing with our product candidates. The outcome following legal assertions of invalidity and unenforceability is unpredictable. With respect to the validity question, for example, we cannot be certain that there is no invalidating prior art, of which we and the patent examiner were unaware during prosecution. If a third party were to prevail on a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection for cretostimogene or any future product candidates. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations and prospects. Patent terms may be inadequate to protect the competitive position of cretostimogene or any future product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional or international patent application filing date. Various extensions may be available, but the life of a

patent, and the protection it affords, is limited. Even if patents covering cretostimogene or any future product candidates are obtained, once the patent has expired, we may be vulnerable to competition from competitive products, including generics. Given the amount of time required for the development, testing and regulatory review of cretostimogene or any future product candidates, patents protecting such product candidates might expire before or shortly after such product candidates are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. If we do not have sufficient patent life to protect our products, our business, financial condition, results of operations and prospects will be adversely affected. If we do not obtain patent term extension and equivalent extensions outside of the United States for cretostimogene or any future product candidates, our business may be materially harmed. Depending upon the timing, duration and specifics of any FDA regulatory approval of cretostimogene or any future product candidates, one or more of our U. S. patents may be eligible for limited patent term extension under the Hatch- Waxman Amendments. The Hatch- Waxman Amendments permit a patent term extension 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. However, we may not be granted an extension for various reasons, including failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or failing to satisfy other applicable requirements. Moreover, the applicable time period afforded could be less than we request. In addition, to the extent we wish to pursue patent term extension based on a patent that we may license from a third party in the future, we may need the cooperation of that third party. If we are unable to obtain patent term extension, or the foreign equivalent, or if the term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations and prospects could be materially harmed. We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may be subject to claims that former employees, consultants, licensees, collaborators or other third parties have an interest in our patent rights, trade secrets, or other intellectual property as an inventor, co- inventor or owner of trade secrets. For example, we may have inventorship or ownership disputes arise from conflicting obligations of consultants or others who are involved in developing cretostimogene or any future product candidates and other proprietary technologies we may develop. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership or our patent rights, trade secrets or other 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 ownership of, or the right to use intellectual property that is important to cretostimogene or any future product candidates and other proprietary technologies we may develop. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patent protection for cretostimogene or any future product candidates and proprietary technologies, we may rely on trade secret protection and confidentiality agreements to protect our unpatented know- how, technology, and other proprietary information and to maintain our competitive position. We seek to protect these trade secrets and other proprietary technology, in part, by entering into non- disclosure and confidentiality agreements with parties who have access to them, such as our employees, licensees, third- party collaborators, CROs, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants. Trade secrets and know- how can be difficult to protect. We cannot guarantee that we have entered into applicable agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. 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. We cannot guarantee that any potential trade secrets and other proprietary and confidential information will not be disclosed or that competitors will not otherwise gain access to trade secrets. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent them from using that technology or information to compete with us. Furthermore, others may independently discover similar trade secrets and proprietary information. If any of our trade secrets were to be disclosed or misappropriated or if any such information were to be independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. We may be subject to claims that third parties have an ownership interest in our trade secrets. For example, we may have disputes arise from conflicting obligations of our employees, consultants or others who are involved in developing cretostimogene or any future product candidates. Litigation may be necessary to defend against these and other claims challenging ownership of our trade secrets. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable trade secret rights, such as exclusive ownership of, or right to use, trade secrets that are important to cretostimogene or any future product candidates and other proprietary technologies we may develop. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may be subject

to claims that our employees, consultants, or advisors have wrongfully used or disclosed alleged trade secrets of their current or former employers or claims asserting ownership of what we regard as our own intellectual property. Some of our employees, consultants and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we try to ensure that our employees, consultants and advisors do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or these individuals have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual' s current or former employer. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to our management. In addition, while it is our policy to require our employees and contractors who may be involved in the conception or development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops intellectual property that we regard as our own. The assignment of intellectual property rights may not be self- executing, or the assignment agreements may be breached, and we may be forced to bring claims against third parties, or defend claims that they may bring against us, to determine the ownership of what we regard as our intellectual property. Such claims could have a material adverse effect on our business, financial condition, results of operations and prospects. We may not identify relevant third- party patents or may incorrectly interpret the relevance, scope or expiration of a third- party patent, which might adversely affect our ability to develop and market cretostimogene or any future product candidates. We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are or will be complete or thorough, nor can we be certain that we have identified or will identify each and every third- party patent and pending patent application in the United States and abroad that is relevant to or necessary for the commercialization of cretostimogene or any future product candidates in any jurisdiction. Patent applications in the United States and elsewhere are not published until approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering cretostimogene or any future product candidates could have been filed by others without our knowledge. The scope of a patent claim is determined by the interpretation of the law, the words of a patent claim, the written disclosure in a patent and the patent' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending patent application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that cretostimogene or any future product candidates 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. Alternatively, we may incorrectly determine that the Hatch- Waxman Amendments are a defense for a safe harbor to infringement of a patent we consider relevant to the research or clinical development of cretostimogene or any future product candidate. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and we may incorrectly conclude that a third- party patent is invalid and unenforceable or not infringed. Our failure to identify and correctly interpret relevant patents may negatively impact our ability to develop and market cretostimogene or any future product candidates. If we fail to identify and correctly interpret relevant patents, we may be subject to infringement claims. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe. As the number of competitors in the market grows and the number of patents issued in this area increases, the possibility of patent infringement claims escalates. Moreover, in recent years, individuals and groups that are non- practicing entities, commonly referred to as " patent trolls, " have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. From time to time, we may receive threatening letters, notices or " invitations to license, " or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing cretostimogene or any future product candidates that are held to be infringing. We might, if possible, also be forced to redesign cretostimogene or any future product candidates or services so that we no longer infringe the third- party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business. Third- party claims of intellectual property infringement, misappropriation, or other violations against us or our collaborators could be expensive and time consuming and may prevent or delay the development and commercialization of cretostimogene or any future product candidates. Our commercial success depends in part on our and our collaborators' ability to avoid infringing, misappropriating and otherwise violating the patents and other intellectual property rights of third parties. There is a substantial amount of complex litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference, derivation and reexamination proceedings before the USPTO or oppositions and other comparable proceedings in foreign jurisdictions. Numerous U. S. and foreign- issued patents and pending patent applications owned by third parties exist in the fields in which we plan to commercialize our therapeutic programs and in which we are developing other proprietary technologies. As the biotechnology and pharmaceutical industries expand and more patents are issued, and as we gain greater visibility and market exposure as a public company, the risk increases that our therapeutic programs and commercializing activities may give rise to claims of infringement of the patent rights of others. We cannot guarantee that our therapeutic programs and other proprietary technologies we develop will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued for which a third party, such as a competitor in the fields in which we are developing our therapeutic programs, might assert as infringed by us. It is also possible that patents owned by third parties of which we are aware, but which we do not believe we

infringe or that we believe we have valid defenses to any claims of patent infringement, could be found to be infringed by us. It is not unusual that corresponding patents issued in different countries have different scopes of coverage, such that in one country a third- party patent does not pose a material risk, but in another country, the corresponding third- party patent may pose a material risk to cretostimogene or any future product candidates. In addition, because patent applications can take many years to issue, there may be currently pending patent applications that may later result in issued patents that we may infringe. For example, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover cretostimogene or any future product candidates or the use of cretostimogene or any such product candidates. In the event that any third- party claims that we infringe their patents or that we are otherwise employing their proprietary technology without authorization and initiates litigation against us, even if we believe such claims are without merit, a court could hold that such patents are valid, enforceable and infringed by us. Defense of infringement claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of management and other employee resources from our business, and may impact our reputation. In the event of a successful claim of infringement against us, we may be enjoined from further developing or commercializing the infringing products or technologies. In addition, we may be required to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties and / or redesign our infringing products or technologies, which may be impossible or require substantial time and monetary expenditure. Such licenses may not be available on commercially reasonable terms or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us might be nonexclusive, which could result in our competitors gaining access to the same intellectual property. If we are unable to obtain a necessary license to a third- party patent on commercially reasonable terms or at all, we may be unable to commercialize the infringing products or technologies or such commercialization efforts may be significantly delayed, which could in turn significantly harm our business. In addition, we may in the future pursue patent challenges with respect to third-party patents, including as a defense against the foregoing infringement claims. The outcome of such challenges is unpredictable. Even if resolved in our favor, the foregoing proceedings could be very expensive, particularly for a company of our size, and time- consuming. Such proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of our competitors may be able to sustain the costs of litigation or administrative proceedings more effectively than we can because of greater financial resources. Such proceedings may also absorb significant time of our technical and management personnel and distract them from their normal responsibilities. Uncertainties resulting from such proceedings could impair our ability to compete in the marketplace. 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. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may in the future pursue invalidity proceedings with respect to third- party patents. The outcome following legal assertions of invalidity is unpredictable. Even if resolved in our favor, these legal proceedings 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 proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing or distribution activities. We may not have sufficient financial or other resources to conduct such proceedings adequately. Some of these third parties may be able to sustain the costs of such proceedings more effectively than we can because of their greater financial resources. Uncertainties resulting from the initiation and continuation of patent proceedings could compromise our ability to compete in the marketplace. If we do not prevail in the patent proceedings the third parties may assert a claim of patent infringement directed at cretostimogene or any future product candidates. We may become involved in lawsuits to protect or enforce our patents and other intellectual property rights, which could be expensive, time- consuming, and unsuccessful. Third parties, such as a competitor, may infringe our patent rights. In an infringement proceeding, a court may decide that a patent we own or a patent we may license in the future is invalid or unenforceable or may refuse to stop the other party from using the invention at issue. In addition, our patent rights may become involved in inventorship, ownership, priority, enforceability, or validity disputes. To counter or defend against such claims can be expensive and time- consuming. An adverse result in any litigation proceeding could put our patent rights at risk of being invalidated, held unenforceable or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation and proceedings, there is a risk that some of our confidential information could be compromised by disclosure during such litigation and proceedings. Even if resolved in our favor, litigation or other legal proceedings relating to intellectual property claims may cause us to incur significant expenses and could distract our 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. 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 and more mature and developed intellectual property portfolios. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings could have a material adverse effect on our ability to compete in the marketplace. 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 registered or unregistered trademarks or trade names may be challenged, infringed, diluted, circumvented or declared generic or determined to be infringing, misappropriating or violating 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 the markets of interest. During trademark registration proceedings, we may receive rejections of our applications by the USPTO or in other foreign jurisdictions. Although we are given an opportunity to respond to such rejections, we may be unable to overcome them. In the event that our trademarks are successfully challenged or determined to be infringing, misappropriating or violating other marks, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote resources to advertising and marketing new brands. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, which may not survive such proceedings. Moreover, any name we may propose to use with cretostimogene or any future product candidates in the United States must be approved by the FDA, regardless of whether we have registered it, or applied to register it, as a trademark. Similar requirements exist in Europe. The FDA typically conducts a review of proposed product names, including an evaluation of potential for confusion with other product names. If the FDA or an equivalent administrative body in a foreign jurisdiction objects to any of our proposed proprietary product names, we may be required to expend significant additional resources in an effort to identify a suitable substitute name that would qualify under applicable trademark laws, not infringe, misappropriate or otherwise violate the existing rights of third parties and be acceptable to the FDA. Furthermore, in many countries, owning and maintaining a trademark registration may not provide an adequate defense against a subsequent infringement claim asserted by the owner of a senior trademark. We may not be able to obtain, protect or enforce our rights to these trademarks and trade names, which we need to build name recognition among potential partners or customers in our markets of interest. At times, competitors or other third parties may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement, misappropriation, dilution or other claims brought by owners of other registered trademarks or trademarks that incorporate variations of our registered or unregistered trademarks or trade names. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to obtain, enforce or protect our proprietary rights related to trademarks, trade names, domain name, or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely affect our business, financial condition, results of operations and prospects. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to cretostimogene or any future product candidates or utilize similar technology but that are not covered by the claims of the patents that we own or may license in the future; • we or our licensors or collaborators might not have been the first to make the inventions covered by our current or future patent applications; • we or our licensors or collaborators might not have been the first to file patent applications covering our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights; • it is possible that our pending and future patent applications that we own or may license will not lead to issued patents; • any issued patent that we own or license in the future may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; • others may have access to the same intellectual property rights licensed to us in the future on a non-exclusive basis; • our competitors or other third parties might conduct research and development activities in countries where we or our licensors do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • we may fail to identify potential patentable subject matter and / or may fail to file on it; • the patents or other intellectual property rights of others may harm our business; and • we may choose not to file for patent protection in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent application covering such intellectual property or disclose information resulting in a loss of protection for such trade secrets. Should any of the foregoing occur, it could adversely affect our business, financial condition, results of operations and prospects. We may not be successful in obtaining or maintaining necessary rights to product components and processes for our development pipeline through acquisitions and in- licenses. The growth of our business may depend in part on our ability to acquire, in- license or use third-party intellectual property and proprietary rights. For example, cretostimogene or any future product candidates may require specific formulations to work effectively and efficiently, we may develop product candidates containing our compounds and pre- existing pharmaceutical compounds, we may develop combination therapies with our compounds and third- party compounds, any of which could require us to obtain rights to use intellectual property held by third parties. In addition, with respect to any patent or other intellectual property rights we may co- own with third parties, we may require licenses to such co-owners' interest to such patents. We may be unable to acquire or in- license any compositions, methods of use, processes or other third- party intellectual property rights from third parties that we identify as necessary or important to our business operations. In addition, we may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. Were that to happen, we may need to cease use of the compositions or methods covered by those third- party intellectual property rights and may need to seek to develop alternative approaches that do not infringe, misappropriate or otherwise violate those intellectual property rights, which may entail additional costs and development delays, even if we were able to develop such alternatives, which may not be feasible. Even if we are able to obtain a license, it may be non- exclusive, which means that our competitors may also receive 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. Additionally, we may collaborate with academic

institutions to accelerate our research and development under written agreements with these institutions. In certain cases, these institutions provide us with an option to negotiate a license to any of the institution' s rights in technology resulting from the collaboration. Even if we hold such an option, we may be unable to negotiate a license from the institution within the specified timeframe or under terms that are acceptable to us. If we are unable to do so, the institution may offer the intellectual property rights to others, potentially blocking our ability to pursue our program. Even if we are able to obtain a license, it may be non- exclusive, and our competitors may also receive access to the same technologies licensed to us. The licensing and acquisition of third- party intellectual property rights is a competitive area, and companies that may be more established or have greater resources than we do may also be pursuing strategies to license or acquire third- party intellectual property rights that we may consider necessary or attractive in order to commercialize cretostimogene or any future product candidates. More established companies may have a competitive advantage over us due to their size, cash resources or greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. There can be no assurance that we will be able to successfully complete these types of negotiations and ultimately acquire the rights to the intellectual property surrounding cretostimogene or any future product candidates that we may seek to develop or market. If we are unable to successfully obtain rights to required third- party intellectual property or to maintain the existing intellectual property rights we have, we may have to abandon development of certain programs and our business, financial condition, results of operations, and prospects could suffer. Risks Related to Ownership of Our Common Stock Prior to our initial public offering, there was no public market for our common stock. An active, liquid and orderly market for our common stock may not ~~develop or~~ be sustained, or we may in the future fail to satisfy the continued listing requirements of Nasdaq. Prior to our initial public offering **in January 2024** , there was no public market for our common stock ~~. Our~~ **and our** common stock only ~~recently~~ began trading on the Nasdaq Global Select Market (Nasdaq) ~~and we~~ **in January 2024. We** can provide no assurance that we will be able to ~~develop~~ **sustain** an active trading market for our common stock. ~~Even if an active market is developed, it may not be sustained.~~ If an active market for our common stock is not sustained, it may be difficult for you to sell your shares at the time you wish to sell them or at a price that you consider reasonable. An inactive market may also impair our ability to raise capital by selling shares and may impair our ability to acquire other businesses or technologies using our shares as consideration, which, in turn, could materially adversely affect our business. ~~.~~ If ~~,~~ we fail to satisfy the continued listing requirements of Nasdaq, 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 the listing requirements of Nasdaq. The trading price of the shares of our common stock could be highly volatile, and purchasers of our common stock could incur substantial losses. Our stock price is likely to be volatile. The stock market in general and the market for stock of 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 at which they paid. The market price for our common stock may be influenced by those factors discussed in this " Risk Factors " section and many others, including: • results of our clinical trials and preclinical studies, and the results of trials of our competitors or those of other companies in our market sector; • our ability to enroll patients in our future clinical trials; • our ability to obtain and maintain regulatory approval of cretostimogene or any future product candidates or additional indications thereof, or limitations to specific label indications or patient populations for its use, or changes or delays in the regulatory review process; • regulatory or legal developments in the United States and foreign countries; • changes in the structure of healthcare payment systems; • the success or failure of our efforts to develop, acquire, or license cretostimogene or any future product candidates; • innovations, clinical trial results, product approvals and other developments regarding our competitors; • announcements by us or our competitors of significant acquisitions, strategic partnerships, joint ventures, or capital commitments; • manufacturing, supply, or distribution delays or shortages; • any changes to our relationship with any manufacturers, suppliers, collaborators or other strategic partners; • achievement of expected product sales and profitability; • variations in our financial results or development timelines or those of companies that are perceived to be similar to us, including variations from expectations of securities analysts or investors; • market conditions in the biopharmaceutical sector and issuance of securities analysts' reports or recommendations; • trading volume of our common stock; • an inability to obtain additional funding; • sales of our stock by us, our insiders or our stockholders ~~, as well as the anticipation of lock- up releases or expiration of market stand- off or lock- up agreements~~ ; • general economic, industry, geopolitical and market conditions, such as military conflict or war, inflation and financial institution instability, or pandemic or epidemic disease outbreaks, many of which are beyond our control; • additions or departures of senior management, directors or key personnel; • intellectual property, product liability or other litigation against us or our inability to enforce our intellectual property; • changes in our capital structure, such as future issuances of securities and the incurrence of additional debt; and • changes in accounting standards, policies, guidelines, interpretations or principles. In addition, in the past, stockholders have initiated class action lawsuits against biopharmaceutical 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, divert our management' s attention and resources and damage our reputation, which could have a material adverse effect on our business, financial condition, results of operations and prospects. Our executive officers, directors, and principal stockholders, if they choose to act together, have the ability to significantly influence all matters submitted to stockholders for approval. As of March ~~25~~ **27** , ~~2024~~ **2025** , our executive officers, directors and greater than 5 % stockholders, in the aggregate, own approximately ~~39~~ **16** . ~~5~~ **7** % of our outstanding common stock. As a result, such persons acting together, have the ability to significantly influence all matters

submitted to our board of directors or stockholders for approval, including the appointment of our management, the election and removal of directors and approval of any significant transaction, as well as our management and business affairs. This concentration of ownership may have the effect of delaying, deferring or preventing a change in control, impeding a merger, consolidation, takeover or other business combination involving us, or discouraging a potential acquiror from making a tender offer or otherwise attempting to obtain control of our business, even if such a transaction would benefit other stockholders. We do not currently intend to pay dividends on our common stock, so any returns on your investment will be limited to the value of our common stock. We have never declared or paid any cash dividend on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring or paying any cash dividends for the foreseeable future. In addition, any future debt agreements may preclude us from paying dividends. Any return to stockholders will therefore be limited to the appreciation of their stock. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which stockholders have purchased their shares. Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock 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 significantly reduce the market price of our common stock and impair our ability to raise adequate capital through the sale of additional equity or equity- linked securities. **Holders** ~~In connection with our initial public offering, our directors and executive officers and substantially all~~ of **a significant number** ~~our securityholders entered into lock- up agreements with the representatives pursuant to which they may not, with limited exceptions, through July 22, 2024, offer, sell or otherwise transfer or dispose~~ of ~~any of our securities, without the prior written consent of Morgan Stanley & Co. LLC and Goldman Sachs & Co. LLC. The underwriters may permit our officers, directors and other securityholders who are subject to the lock- up agreements to sell~~ shares ~~prior to the expiration~~ of ~~the lock- up agreements at any time in their sole discretion. Sales of these shares, or~~ **our** ~~perceptions that they will be sold, could cause the trading price of our common stock to decline. After the lock- up agreements expire, these shares of common stock will be eligible for sale in the public market, except that shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act. In addition, as of December 31, 2023, 5, 222, 283 shares of common stock that are subject to~~ outstanding ~~options under our employee benefit plans will become eligible for sale in the public market to the extent permitted by the provisions of various vesting schedules, the lock- up agreements and Rule 144 and Rule 701 under the Securities Act. If these additional shares of~~ common stock are ~~sold, or if it is perceived that they will be sold, in the public market, the trading price of our common stock could decline. The holders of 38, 413, 913 shares of our outstanding common stock, or approximately 57. 6 % of our total outstanding common stock based on shares outstanding as of March 25, 2024, will be~~ entitled to rights with respect to the registration of their shares under the Securities Act, subject to vesting ~~and the 180- day lock- up agreements described above~~. Any sales of securities by these stockholders could have a material adverse effect on the trading price of our common stock. We are an emerging growth company ~~and a smaller reporting company~~, and the reduced disclosure requirements applicable to emerging growth ~~companies and smaller reporting~~ companies may make our common stock less attractive to investors. We are an emerging growth company, as defined in the JOBS Act, and may remain an emerging growth company until the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering. However, if certain events occur prior to the end of such five- year period, including if we become a " large accelerated filer ", as defined under the Exchange Act, our annual gross revenue exceeds $ 1. 235 billion or we issue more than $ 1. 0 billion of non- convertible debt in any three- year period, we will cease to be an emerging growth company prior to the end of such five- year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include: • being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced " Management' s Discussion and Analysis of Financial Condition and Results of Operations " disclosure; • not being required to comply with the auditor attestation requirements in the assessment of our internal control over financial reporting pursuant to the Sarbanes- Oxley Act of 2002 (Sarbanes- Oxley); • 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, unless the SEC determines the new rules are necessary for protecting the public; • reduced disclosure obligations regarding executive compensation; and • exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict whether investors will find our common stock less attractive if we 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 reduced or more volatile. In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of these accounting standards until they would otherwise apply to private companies. We have irrevocably elected to avail ourselves of this exemption and, therefore, we may not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies. We intend to rely on other exemptions provided by the JOBS Act, including without limitation, not being required to comply with the auditor attestation requirements of Section 404 (b) of Sarbanes- Oxley. ~~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 and will be able to take advantage of these scaled disclosures for so long as our voting and non- voting common stock held by non- affiliates is less than $ 250. 0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $ 100. 0 million during the most recently completed fiscal year and our voting and non- voting common stock held by non- affiliates is less than $ 700. 0 million measured on the last business~~

~~day of our second fiscal quarter.~~ Provisions in our charter documents and under Delaware law could discourage a takeover that stockholders may consider favorable and may lead to entrenchment of management. Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that could significantly reduce the value of our shares to a potential acquiror or delay or prevent changes in control or changes in our management without the consent of our board of directors. The provisions in our charter documents include the following: • a classified board of directors with three- year staggered terms, which may delay the ability of stockholders to change the membership of a majority of our board of directors; • no cumulative voting in the election of directors, which limits the ability of minority stockholders to elect director candidates; • the exclusive right of our board of directors, unless the board of directors grants such right to the stockholders, to elect a director to fill a vacancy created by the expansion of the board of directors or the resignation, death or removal of a director, which prevents stockholders from being able to fill vacancies on our board of directors; • the required approval of at least 66- 2 / 3 % of the shares entitled to vote to remove a director for cause, and the prohibition on removal of directors without cause; • the ability of our board of directors to authorize the issuance of shares of preferred stock and to determine the price and other terms of those shares, including preferences and voting rights, without stockholder approval, which could be used to significantly dilute the ownership of a hostile acquiror; • the ability of our board of directors to alter our amended and restated bylaws without obtaining stockholder approval; • the required approval of at least 66- 2 / 3 % of the shares entitled to vote to adopt, amend or repeal our amended and restated bylaws or repeal the provisions of our amended and restated certificate of incorporation regarding the election and removal of directors; • a prohibition on stockholder action by written consent, which forces stockholder action to be taken at an annual or special meeting of our stockholders; • an exclusive forum provision providing that the Court of Chancery of the State of Delaware will be the exclusive forum for certain actions and proceedings; • the requirement that a special meeting of stockholders may be called only by the board of directors, which may delay the ability of our stockholders to force consideration of a proposal or to take action, including the removal of directors; and • advance notice procedures that stockholders must comply with in order to nominate candidates to our board of directors or to propose matters to be acted upon at a stockholders' meeting, which may discourage or deter a potential acquiror from conducting a solicitation of proxies to elect the acquiror' s own slate of directors or otherwise attempting to obtain control of us. We are also subject to the anti- takeover provisions contained in Section 203 of the Delaware General Corporation Law. Under Section 203, a corporation may not, in general, engage in a business combination with any holder of 15 % or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders and that the federal district courts shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees or the underwriters or any offering giving rise to such claim. Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is the exclusive forum for any derivative action or proceeding brought on our behalf, any action asserting a breach of fiduciary duty, any action asserting a claim against us arising pursuant to the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws, or any action asserting a claim against us that is governed by the internal affairs doctrine; provided, that, this provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act. or any other claim for which the federal courts have exclusive jurisdiction. Furthermore, our amended and restated certificate of incorporation also provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. These choice of 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 such lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. By agreeing to this provision, however, stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation has been challenged in legal proceedings, and it is possible that a court could find these types of provisions to be inapplicable or unenforceable. If a court were to find the choice of forum provisions in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our business and financial condition. General Risk Factors We incur significant costs as a result of operating as a public company, and our management is required to devote substantial time to new compliance initiatives. As a public company, we incur significant legal, accounting and other expenses that we did not incur as a private company. We are subject to the reporting requirements of the Exchange Act, which requires, among other things, that we file with the SEC annual, quarterly and current reports with respect to our business and financial condition. In addition, Sarbanes- Oxley, as well as rules subsequently adopted by the SEC and Nasdaq to implement provisions of Sarbanes- Oxley, impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and certain corporate governance practices. Further, pursuant to the Dodd- Frank Wall Street Reform and Consumer Protection Act of 2010, the SEC has adopted additional rules and regulations in these areas, such as mandatory " say on pay " voting requirements that will apply to us when we cease to be an emerging growth company. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. We expect the rules and regulations applicable to public companies to substantially increase our legal and financial compliance costs and to make some activities more time consuming and costly. The increased costs will decrease our net income or increase our net loss, and may require us to reduce expenditures in other

areas of our business. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to incur substantial costs to maintain the same or similar coverage. We cannot predict or estimate the amount or timing of additional costs we may incur to comply with these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees or as executive officers. If these requirements divert the attention of our management and personnel from other business concerns, they could have a material adverse effect on our business, financial condition, results of operations and prospects. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. We could face criminal liability and other serious consequences for violations, which could harm our business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, and various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls and anti- corruption and anti- money laundering laws and regulations, including the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, CROs, contractors and other collaborators and partners from authorizing, promising, offering, providing, soliciting or receiving, directly or indirectly, improper payments or anything else of value to or from recipients in the public or private sector. We may engage third parties for clinical trials outside of the United States, to sell our products abroad if and when we enter a commercialization phase, and / or to obtain necessary permits, licenses, patent registrations and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, CROs, contractors and other collaborators and partners, even if we do not explicitly authorize or have actual knowledge of such activities, and any training or compliance programs or other initiatives we undertake to prevent such activities may not be effective. Any violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm and other consequences. Furthermore, U. S. export control laws and economic sanctions prohibit the provision of certain products and services to countries, governments, and persons targeted by U. S. sanctions. U. S. sanctions that have been or may be imposed may impact our ability to continue activities at future clinical trial sites within regions covered by such sanctions. If we fail to comply with export and import regulations and such economic sanctions, penalties could be imposed, including fines and / or denial of certain export privileges. These export and import controls and economic sanctions could also adversely affect our supply chain. We and any of our third- party manufacturers or suppliers may use potent chemical agents and hazardous materials, and any claims relating to improper handling, storage, or disposal of these materials could be time- consuming or costly. We and any of our third- party manufacturers or suppliers and our current or any future collaborators may use biological materials, potent chemical agents, and hazardous materials, including chemicals and biological agents and compounds that could be dangerous to human health and safety of the environment. Our operations and the operations of our third- party manufacturers and suppliers also produce hazardous waste products. Federal, state and local laws and regulations govern the use, generation, manufacture, storage, handling and disposal of these materials and wastes. Compliance with applicable environmental laws and regulations may be expensive, and current or future environmental laws and regulations may impair our product development efforts. In addition, neither we or our third- party manufacturers and suppliers can eliminate the risk of accidental injury or contamination from these materials or wastes. 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. In the event of contamination or injury at our, our manufacturers' or our suppliers' sites, 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. Although we maintain workers' compensation insurance for certain costs and expenses we may incur due to injuries to our employees resulting from work- related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not maintain insurance for toxic tort claims that may be asserted against us in connection with the storage or disposal of biologic, hazardous or radioactive materials. In addition, we may incur substantial costs in order to comply with current or future environmental, health, and safety laws and regulations, which have tended to become more stringent over time. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions or liabilities, which could materially adversely affect our business, financial condition, results of operations and prospects. Business disruptions could seriously harm our future revenue and financial condition and increase our costs and expenses. Our operations and the operations of our manufacturers, suppliers, collaborators, CROs and clinical sites could be subject to earthquakes, power shortages, telecommunications or infrastructure failures, cybersecurity incidents, physical security breaches, water shortages, floods, hurricanes, typhoons, blizzards and other extreme weather conditions, fires, public health pandemics or epidemics (including, for example, the COVID- 19 pandemic) and other natural or manmade disasters or business interruptions, for which we are predominantly self- insured. We rely on third- party manufacturers or suppliers to produce cretostimogene or any future product candidates and its components and on CROs and clinical sites to conduct our clinical trials, and do not have a redundant source of supply for all components of cretostimogene or any future product candidates. Our ability to obtain clinical or, if approved, commercial, supplies of cretostimogene or any future product candidates could be disrupted if the operations of these suppliers were affected by a man- made or natural disaster or other business interruption, and our ability to commence, conduct or complete our clinical trials in a timely manner could be similarly adversely affected by any of the foregoing. In addition, our corporate headquarters is located in Irvine, California near major earthquake faults and fire zones,

and the ultimate impact on us of being located near major earthquake faults and fire zones and being consolidated in a certain geographical area is unknown. The occurrence of any of these business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. Unstable market and economic conditions and adverse developments with respect to financial institutions and associated liquidity risk may have serious adverse consequences on our business, financial condition and stock price. From time to time, the global credit and financial markets have experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. The financial markets and the global economy may also be adversely affected by the current or anticipated impact of military conflict, including the conflicts between Russia and Ukraine and in the Middle East, terrorism or other geopolitical events **, including threatened or actual trade wars and tariffs** . Sanctions imposed by the United States and other countries in response to such conflicts, including the one in Ukraine, may also adversely impact the financial markets and the global economy, and any economic countermeasures by the affected countries or others could exacerbate market and economic instability. In addition, in 2023 the closures of financial institutions and their placement into receivership with the FDIC created bank- specific and broader financial institution liquidity risk and concerns. Future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market- wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short- term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to delay, limit, reduce or abandon product development or future commercialization efforts or grant rights to develop and market our product candidates even if we would otherwise prefer to develop and market such product candidates ourselves. In addition, there is a risk that one or more of our current service providers, financial institutions, manufacturers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget. Changes in tax law may materially adversely affect our financial condition, results of operations and cash flows, or adversely impact the value of an investment in our common stock. New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us, any of which could adversely affect our business operations and financial performance. **Changes in corporate tax rates, the realization of net deferred tax assets relating to our operations, the taxation of foreign earnings, and the deductibility of expenses or future reform legislation could have a material impact on the value of our deferred tax assets, could result in significant one- time charges, and could increase our future U. S. tax expense.** If securities or industry analysts do not publish research or reports or publish unfavorable research or reports about our business, our stock price and trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us, our business, our market or our competitors. If one or more of the analysts who covers us downgrades our stock, or if we fail to meet the expectations of one or more of these analysts, our stock price would likely decline. If one or more of these analysts ceases to cover us or fails to regularly publish reports on us, interest in our stock could decrease, which could cause our stock price or trading volume to decline. If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, investors may lose confidence in our financial reporting and the trading price of our common stock may decline ~~. Pursuant to Section 404 of Sarbanes- Oxley, our management will be required to report upon the effectiveness of our internal control over financial reporting beginning with the second annual report following the completion of our initial public offering~~ . When we lose our status as an " emerging growth company **,** " ~~and do not otherwise qualify as a " smaller reporting company " with less than $ 100. 0 million in annual revenue,~~ our independent registered public accounting firm will be required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that ~~must be met for~~ our management **are required to meet** to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our information technology systems; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. If we or, if required, our auditors are unable to conclude that our internal control over financial reporting is effective, investors may lose confidence in our financial reporting and the trading price of our common stock may decline. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal control over financial reporting in the future. Any failure to maintain internal control over financial reporting could severely inhibit our ability to accurately report our financial condition, results of operations or cash flows. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting once that firm begins its Section 404 reviews, investors may lose confidence in the accuracy and completeness of our financial reports, the market price of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also restrict our future access to the capital markets. We could be subject to securities class action litigation. In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology and biopharmaceutical companies

have experienced significant stock price volatility in recent years. If we face such litigation, even if ultimately decided in our favor, it could result in substantial costs and a diversion of our management' s attention and resources, which could harm our business. 88