Risk Factors Comparison 2025-03-03 to 2024-02-28 Form: 10-K

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

Investing in our securities involves a high degree of risk. This section includes a discussion of what we believe to be the material factors that make an investment in our Company speculative or risky. The risks described in this section are not the only risks we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial also may impair our business operations and the market price of our securities. You should carefully consider the risks described below, as well as other information contained in this Annual Report on Form 10- K, including our consolidated financial statements and the related notes and the section titled " Management' s Discussion and Analysis of Financial Condition and Results of Operations, " before deciding whether to invest in our securities. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations, and growth prospects. In such an event, the market price of our securities could decline, and you may lose all or part of your investment. Risks Related to the Discovery, Development, and Commercialization of Our Product Candidates ● We have ~~concentrated a substantial portion of our research and~~ **no approved products. Our product candidates are subject to significant** development **risks** ~~efforts on the treatment of Alzheimer' s disease~~ , ~~an~~ **and we may never achieve regulatory approval** ~~area of research that has seen significant failure rates. Further, our~~ - **or commercial success. ● Our** product candidates are based on new scientific approaches and novel technology, which makes it difficult to predict the time and cost of product candidate development and likelihood of success. ● **The drug development process, the clinical trial process and the enrollment and retention of patients in clinical trials could be challenging, expensive and time- consuming for the indications that we are targeting. ●** We are heavily dependent on the success of simufilam, our lead product candidate which is ~~still~~ under development. If this product candidate **is unsuccessful in clinical development** ~~fails one or both of our ongoing Phase 3 trials~~ , or does not receive regulatory approval, we will be unable to generate product revenue and our business will be harmed. ● We have a limited operating history in our business targeting Alzheimer' s disease **and TSC- related epilepsy** and no history of product approvals for commercial sale, which may make it difficult to evaluate our current business and predict our future success and viability. ● We cannot give any assurance that we will file for regulatory approval for any of our product candidates, or that if we file for approval, our product candidates will receive regulatory approval, which is necessary before they can be commercialized. ● ~~There can be no assurance that promising results~~ **Results** ~~of smaller Phase 1 and Phase 2~~ **observed in preclinical studies, early stage** clinical trials ~~or~~ **for** ~~24- month safety study with simufilam will be reproduced in our large Phase 3 studies. ● Clinical results observed in our smaller Phase 1 and Phase 2 clinical trials or 24- month safety study with~~ simufilam are not regulatory evidence of drug safety or efficacy. ● We may encounter substantial delays in ~~our~~ clinical studies **that we conduct** or may not be able to conduct or complete ~~our~~ clinical studies on the timelines we expect, if at all. ● If physicians and patients do not accept and use our drugs, we will not achieve sufficient product revenues and our business will suffer. ● We currently have no in- house capabilities to manufacture or commercialize our product candidates, and we rely on a third- party commercial drug manufacturing organization for ~~clinical drug~~ supplies **of simufilam** . If we are unable to develop our own manufacturing, sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, our product revenues could be adversely impacted. ● ~~We may need to rely on clinical~~ **Clinical** ~~results generated predominately, or even solely, from patients with mild Alzheimer' s disease to show evidence of efficacy in our Phase 3 clinical trials, if any, and this may present more or different challenges in our efforts to develop simufilam. ● Our clinical~~ studies **that we conduct** may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization. Risks Related to Government Regulation and Other Legal Compliance Matters ● Our financial condition and operating results could be adversely impacted by unfavorable results of legal proceedings, government investigations or allegations and other claims ~~, many of which arose following a short selling attack campaign against our Company that commenced in 2021~~ . ● If we are ultimately unable to file for and obtain regulatory approval for our product candidates, we will be unable to generate product revenue and our business will be substantially harmed. ● Our ability to market and promote our product candidates will be determined and limited by FDA- approved labeling. ● If we fail to comply or stay in compliance with the complex set of federal, state, local and foreign laws and regulations that apply to our business, we could suffer severe consequences that could materially and adversely affect our operating results and financial condition. ● Government agencies may establish and promulgate usage guidelines that could limit the use of our product candidates. Risks Related to Our Intellectual Property ● If we are unable to obtain and maintain sufficient patent protection for any product candidates we develop, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop may be adversely affected. ● Issued patents covering our product candidates and other technologies could be found invalid or unenforceable if challenged in court or before administrative bodies in the U. S. or abroad. ● If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed. ● If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be materially harmed. Risks Related to Our Business and Operations ● **The validity** ~~Our reputation and operations could be adversely impacted by allegations~~ of **aspects** ~~wrongdoing, regardless~~ of ~~their~~ -- **the** ~~merits~~ **Company' s Phase 2b Study has been called into question. ● We are subject to lawsuits and governmental investigations and inquiries** . ● Our ability ~~to continue~~ to operate without any significant disruptions will, in part, depend on our ability to source materials and clinical supplies via our product supply chains. ● Our reliance on third parties for both the supply and manufacture of materials for our product candidates carries the risk that we will not have

sufficient quality or quantities of such materials or product candidates, or that such supply will not be available to us at an acceptable cost, which could delay, prevent, or impair our development or commercialization efforts. ● **Our Workforce Reduction** ~~We expect to significantly grow the size and capabilities of our organization and we~~ may **result** ~~experience difficulties~~ in ~~effectively managing this growth~~ **operational and strategic challenges** . ● Our internal computer systems, or those used by third parties on whom we rely, may fail or suffer other breakdowns, cyberattacks, or information security breaches that could compromise the confidentiality, integrity, and availability of such systems and data, result in material disruptions of our development programs and business operations, risk disclosure of confidential, financial, or proprietary information, and affect our reputation. ● Business disruptions and lack of appropriate levels of commercial insurance could seriously harm our future revenue and financial condition and increase our costs and expenses. ● Social media platforms have significantly altered the dynamics of corporate communications and present risks and challenges, some of which are and may continue to be unknown to us. Risks Related to Financial Condition and Capital Requirements ● We have incurred significant net losses in each period since our inception and anticipate that we will continue to incur net losses for the foreseeable future. ● We have broad discretion in the use of our capital resources, including the net proceeds from any of our financing transactions and may not use them effectively. ● We have no product revenues and may never achieve revenues or profitability based on product revenues. Risks Related to the Ownership of Our Common Stock ● The market price of our common stock has historically been highly volatile and we expect it to continue to be volatile, which could result in substantial losses for investors who purchase our shares. ● Changes in our ownership could limit our ability to utilize net operating loss carryforwards. ~~● Short sellers of our stock may be manipulative and may drive down the market price of our common stock.~~ We **have no approved products. Our product candidates are subject to significant development risk, and we may never achieve regulatory approval or commercial success We are developing therapeutic and diagnostic product candidates, but to date have no approved products and** have concentrated substantially all of our **resources in recent years on** research and development efforts on experimental methods for the treatment of Alzheimer' s disease. **As we explore expansion into** ~~Prior efforts by biopharmaceutical companies in the~~ **other therapeutic indications** ~~field of neurodegenerative diseases~~ , ~~including efforts~~ **we expect that we will continue to expend substantial resources on research and development. All of the product candidates that we seek** to develop **are subject to significant development risk, as the development of** new **pharmaceutical** treatments **is inherently risky. Developing and, if approved, commercializing a novel treatment** for **a central nervous system disorder, such as** Alzheimer' s disease **or TSC** ~~, have seen many failures and very limited clinical success. Since 2003, many new types and classes of drugs have been developed and tested in Alzheimer' s disease, including monoclonal antibodies, gamma secretase modulators and inhibitors, β~~ **related epilepsy** ~~site amyloid precursor protein cleaving enzyme (BACE) inhibitors~~ , ~~receptor for advanced glycation end- products (RAGE) inhibitors, nicotinic partial agonists and allosteric modulators, serotonin subtype receptor (5HT6) antagonists, and others, but virtually all of these scientific programs have failed in Phase 3 or earlier testing. Developing and, if approved, commercializing a novel treatment for Alzheimer' s disease~~ subjects us to many challenges, including obtaining regulatory approval from FDA and other regulatory authorities ~~who have only a limited set of precedents to rely on~~ . ~~Notwithstanding~~ **Because of** the ~~substantial~~ challenges ~~historically~~ associated with ~~the~~ **drug** development ~~of new treatments~~ **, we may never achieve regulatory approval or commercial success** for **any** ~~Alzheimer' s disease, we seek to improve brain health by addressing the neurodegeneration and neuroinflammation components~~ of ~~Alzheimer' s disease~~ **the product candidates that we develop** . Our lead drug candidate **, simufilam,** ~~for Alzheimer' s disease~~ is based on a new approach of stabilizing — but not removing — a critical protein in the brain. We cannot be certain that our novel technologies will yield clinical results that support the approval of a safe and effective therapeutic product or, if approvable, that such a product will be marketable. In addition, because FDA has limited comparators to evaluate our lead drug candidate, we could experience a longer than expected regulatory review process and increased development costs. **The drug development process, the clinical trial process and the enrollment and retention of patients in clinical trials could be challenging, expensive and time- consuming for the indications that we are targeting. Identifying and qualifying patients to participate in clinical studies is critical to the success of the relevant product candidate. The timing of clinical studies depends, in part, on the speed of recruitment of patients to participate in testing such product candidates as well as completion of required follow- up periods. We may not be able to identify, recruit and enroll a sufficient number of patients or patients with required or desired characteristics to achieve the objectives of the study. If patients are unable or unwilling to participate in such studies, the timeline for recruiting patients, conducting studies and obtaining regulatory approval of potential products may be delayed. These delays could result in increased costs, delays in advancing our product candidates, delays in testing the effectiveness of our technology, failure to meet study endpoints or objectives or termination of the clinical studies altogether. Patient enrollment and retention in clinical trials depends on many factors, including the size of the patient population, the nature of the trial protocol, the existing body of safety and efficacy data, the number and nature of competing treatments and ongoing clinical trials of competing therapies for the same indication, the proximity of patients to clinical sites and the eligibility criteria for the trial. Such enrollment issues could cause delays or prevent development and approval of our drug candidate. Furthermore, our efforts to build relationships with patient communities may not succeed, which could result in delays in patient enrollment in our clinical trials. In addition, any negative results we may report in clinical trials of our drug candidate may make it difficult or impossible to recruit and retain patients in other clinical trials of that same drug candidate. For example, our enrollment efforts for future clinical trials, regardless of indication, may face headwinds as a result of the failure of our RETHINK-ALZ clinical trial to achieve its primary endpoints. To the extent that we pursue an indication for simufilam for TSC-related epilepsy, we may face particular challenges. Because TSC is a rare neurological disorder, there are limited patient pools from which to draw in order to complete clinical trials in a timely and cost- effective manner. Identifying and qualifying patients to participate in our clinical trials would be critical to our success in pursuing an indication in**

TSC for simufilam. The number of patients suffering from TSC is small and has not been established with precision. If the actual number of patients with TSC is smaller than we anticipate, we may encounter difficulties in enrolling patients in our clinical trials, thereby delaying or preventing development and approval of a drug candidate. Even once enrolled we may be unable to retain a sufficient number of patients to complete trials for TSC- related epilepsy. Delays or failures in planned patient enrollment or retention may result in increased costs, program delays or both, which could have a harmful effect on our ability to develop our drug candidates or could render further development impossible. We are heavily dependent on the success of simufilam, our lead product candidate **,** which is ~~still~~ under development. If this product candidate **is unsuccessful in** ~~fails one or both of our on- going Phase 3~~ clinical **development** ~~trials,~~ or does not receive regulatory approval, we will be unable to generate product revenue and our business will be harmed ~~. In recent years, we have invested a significant portion of our efforts and financial resources in the development of simufilam and, to a much lesser extent, SavaDx, for the treatment and detection of Alzheimer' s disease, respectively~~ . Our business is substantially dependent on our ability to successfully complete clinical development and obtain regulatory approval for simufilam, which may never occur. **In recent years, we have invested a significant portion of our efforts and financial resources in the development of simufilam and, to a much lesser extent, SavaDx, for the treatment and detection of Alzheimer' s disease, respectively. We also intend to conduct exploratory preclinical studies to better understand simufilam' s potential as a treatment for TSC- related seizures.** The results of clinical studies are subject to a variety of factors, and there can be no assurance **for any indication** that simufilam will **achieve clinical success,** advance to regulatory approval, be approved by applicable regulatory agencies, or be successfully commercialized. ~~We expect~~ **An unfavorable outcome in one or more of the clinical trials** that **we conduct would** ~~a substantial portion of our efforts and expenditures over the next few years will continue to~~ be ~~devoted to simufilam and, to~~ a **major setback** ~~much lesser extent, SavaDx. This will require additional clinical development, management of clinical and manufacturing activities, regulatory approval in one or~~ **for** ~~more national jurisdictions and obtaining commercial- scale manufacturing supply. Substantial investment and significant efforts will be required before we can generate any revenues from any commercial sales of~~ our product candidates **and for us and may require us to delay, reduce or re- define the scope of, or eliminate one or more product candidate development programs, any of which could have a material adverse effect on our business, financial condition and prospects** . ~~We cannot be certain~~ **For example, on November 25, 2024, we announced** that **the topline results from our Phase 3 RETHINK- ALZ study of simufilam in Alzheimer' s disease did not meet each of the pre- specified co- primary, secondary and exploratory biomarker endpoints. Following the failure of REITHINK- ALZ,** we **discontinued our Phase 3 REFOCUS- ALZ study as** ~~will~~ **well** ~~be able~~ **as all of our open- label extension studies in Alzheimer' s disease. Following the release of the topline REFOCUS- ALZ results, we intend** to ~~successfully complete~~ **evaluate the results and determine the next steps for the future advancement, if** any **,** of ~~these activities~~ **its Alzheimer' s program** . We are a clinical- stage biopharmaceutical company with a limited operating history in our business **initially** targeting Alzheimer' s disease **and now evaluating TSC- related epilepsy as a target** . Since we commenced operations in 1998, we have had no product candidates approved for commercial sale and have not generated any revenue from product sales. Drug development is a highly uncertain undertaking and involves a substantial degree of risk. To date, we have not completed a **successful** pivotal Phase 3 clinical study in Alzheimer' s disease **or TSC- related epilepsy** , obtained marketing approval for any product candidates, or conducted sales and marketing activities necessary for successful product commercialization. Our long operating history as a company without product revenue makes any assessment of our future success and viability subject to significant uncertainty. We will continue to encounter risks and difficulties frequently experienced by clinical- stage biopharmaceutical companies in rapidly evolving fields. We have not yet demonstrated an ability to successfully overcome such risks and difficulties. If we do not successfully address these risks and difficulties, our business, results of operations and financial condition will suffer materially. We cannot give any assurance that **we will file for regulatory approval for** any of **our product candidates or that, if we file for approval,** our product candidates will receive regulatory approval, which is necessary before they can be commercialized. To date, we have invested substantial effort and financial resources to identify, procure intellectual property for, and develop our programs in neurodegeneration **and other central nervous system disorders** , including conducting preclinical and clinical studies for our product candidates, simufilam and SavaDx, and providing general and administrative support for these operations. Our future success is dependent on our ability to successfully develop, obtain regulatory approval for, and then successfully commercialize our product candidates, and we may fail to do so for many reasons, including the following: ● our product candidates may not successfully complete preclinical studies or clinical studies **, as recently occurred with our RETHINK- ALZ Phase 3 clinical study** ; ● a product candidate may, on further study, be shown to have harmful side effects or other characteristics that indicate it is unlikely to be safe or effective or otherwise does not meet applicable regulatory criteria; ● our competitors may develop products or therapies that render our product candidates obsolete or less attractive; ● the product candidates that we develop may not be sufficiently covered by intellectual property; ● the product candidates that we develop may be challenged by third parties' patents or other intellectual property or exclusive rights; ● the market for our product candidates may change so that the continued development of a product candidate is no longer reasonable or commercially attractive; ● our product candidates may not be capable of being produced in commercial quantities at an acceptable cost, or at all; ● if a product candidate obtains regulatory approval, we may be unable to establish sales and marketing capabilities, or successfully market such approved product candidate, to gain market acceptance; and ● a product candidate may not be accepted as safe, effective or useful by patients, the medical community or third- party payors, if applicable. If any of these events occur, we may be forced to abandon our development efforts for a program or programs, which would have a material adverse effect on our business and could potentially cause us to cease operations. We may not be successful in our efforts to further develop our product candidates. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. SavaDx is in the early stages

of development. Simufilam, our **lead** ~~late- stage~~ product candidate, will require successful completion of **a** ~~our ongoing~~ Phase 3 program, management of preclinical, clinical, and manufacturing activities, regulatory approval, adequate manufacturing supply, a commercial organization, and significant marketing efforts before we generate any revenue from product sales, if at all. We have never completed a product development program in neurodegeneration **or other central nervous system disorders** . Further, we cannot be certain that any of our product candidates will be successful in clinical studies, and we may terminate existing or future clinical studies prior to their completion **, as occurred with our REFOCUS- ALZ Phase 3 clinical trial and open- label extension trials for Alzheimer' s disease following the failure of our RETHINK- ALZ Phase 3 clinical trial to achieve its pre- specified endpoints** . If any of our product candidates successfully complete clinical studies, we may seek regulatory approval to market our product candidates in the U. S., Japan, Canada, the United Kingdom or the European Union, and in additional foreign countries where we believe there is a viable commercial opportunity. We may never receive regulatory approval to market any product candidates anywhere even if such product candidates successfully complete clinical studies, which would adversely affect our viability. To obtain regulatory approval in countries outside the U. S., we would need to comply with numerous and varying regulatory requirements of such other countries regarding safety, efficacy, manufacturing and controls, clinical studies, commercial sales, pricing, and distribution of our product candidates. Even if we are successful in obtaining approval in one jurisdiction, we cannot ensure that we will obtain approval in any other jurisdictions. If we are unable to obtain approval for our product candidates in multiple jurisdictions, our business, financial condition, results of operations, and our growth prospects could be negatively affected. Even if we receive regulatory approval to market any of our product candidates, whether for the treatment or diagnosis of neurodegenerative diseases or other diseases, we cannot provide assurance that any such product candidate will be successfully commercialized, widely accepted in the marketplace or more effective than other commercially available alternatives. Investment in biopharmaceutical product development involves significant risk that any product candidate will fail to demonstrate adequate efficacy or an acceptable safety profile, gain regulatory approval, and become commercially viable. We cannot provide any assurance that we will be able to successfully advance any of our product candidates through the development process or, if approved, successfully commercialize any of our product candidates. There can be no assurance that promising results of ~~smaller~~ **preclinical studies or** Phase 1 ~~and~~ **or** Phase 2 clinical trials ~~or a 24- month Safety Study~~ with simufilam will be reproduced in ~~our large~~ **later stage studies, including** Phase 3 studies. Results of **any of our preclinical studies** ~~our~~ **or** Phase 1 ~~,~~ **or** Phase 2 **clinical trials** ~~and 24- month Safety Study~~ with simufilam are not predictive of the future results of **any other trial, including any later- stage** Phase 3 clinical trials. **Notwithstanding promising results in earlier stage trials, our first Phase 3 trial in Alzheimer' s disease did not meet each of the pre- specified co- primary, secondary and exploratory biomarker endpoints.** Simufilam may fail to show the desired safety and efficacy in **additional** Phase 3 clinical trials despite having progressed successfully through preclinical studies and initial clinical trials **in the applicable indication** . Many biopharmaceutical companies have suffered significant setbacks in Phase 3 clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. We cannot be certain that our product candidates will not **continue to** face similar setbacks. In addition, **preliminary** conclusions based on data from analyses of Phase 1 and Phase 2 clinical studies and open- label results may not be reproduced when implemented in large, well- controlled, randomized clinical trials. Particular caution should be exercised when interpreting preliminary data, data relating to a small number of patients and data from open- label uncontrolled studies, which are generally not capable of providing interpretable evidence of efficacy. ~~Results of our small, " first- in- human "~~ Phase 1 ~~study was~~ **studies are** designed to assess the initial safety characteristics of simufilam ~~in healthy human volunteers~~ and ~~this study was~~ **such studies are** not designed to, and ~~did~~ **do** not, evaluate safety, tolerability and efficacy of simufilam in patients. Similarly, ~~our~~ Phase 2 clinical studies with simufilam ~~were~~ **that we conduct are** designed to assess the safety characteristics of simufilam in patients. ~~Our~~ **Such** Phase 2 ~~program~~ **programs** ~~was~~ **are** not designed to, and ~~did~~ **do** not, evaluate large- scale or long- term safety, tolerability and efficacy of simufilam in patients. There can be no assurance that future large, well- controlled, multi- dose studies will demonstrate the safety, tolerability or efficacy of simufilam to treat patients with any indication, including Alzheimer' s disease **or TSC- related epilepsy** . Even if ~~our~~ clinical trials for simufilam are completed ~~as planned~~ , we cannot be certain that their results will support the substantial evidence of safety and efficacy needed to obtain regulatory approval. The failure of simufilam to show safety, tolerability or efficacy in any future clinical studies would significantly harm our business. ~~Clinical results~~ **Results** observed **preclinical studies** ~~our smaller Phase 1~~ and ~~Phase 2~~ **early- stage** clinical trials ~~or for 24- month Safety Study with~~ simufilam are not regulatory evidence of drug safety or efficacy. Data results from ~~our~~ **any preclinical and** non- Phase 3 studies **that we conduct** do not constitute, and should not be interpreted as, regulatory evidence of safety or efficacy for simufilam in **the applicable indication, including** Alzheimer' s disease **or TSC- related epilepsy** . Rigorous evidence for drug safety and efficacy is derived **only** from one or more large, randomized, placebo- controlled studies. The size and open- label design of portions of our non- Phase 3 studies may introduce clinical or statistical bias or may generate results that may not fully distinguish between drug effects and random variation. Different methods of statistical analysis on clinical data from the same study may lead to objectively different numerical results. These and other statistical and clinical features of our non- Phase 3 studies add complexity or limitations to the scope of data interpretation **. We may encounter substantial delays in the clinical studies that we conduct or may not be able to conduct or complete our clinical studies on the timelines we expect, if at all** . Clinical testing is expensive, time consuming, and subject to uncertainty. We cannot guarantee that any clinical studies will be conducted as planned, enroll patients as planned or be completed on schedule, if at all. Moreover, even after our studies begin, safety or other issues may arise that could suspend or terminate such clinical studies. A failure of one or more clinical studies can occur at any stage of testing, and our ongoing or future clinical studies may not be successful. Events that may prevent successful or timely initiation or completion of clinical studies include: ● inability to generate sufficient or necessary preclinical, toxicology, or other in vivo or in vitro data to support the initiation or continuation of clinical studies or to support the filing of a New Drug Application for simufilam; ● delays in confirming target engagement, patient selection, or other relevant biomarkers

to be utilized in preclinical and clinical product candidate development; ● delays in reaching a consensus with regulatory agencies on study design; ● delays in reaching an agreement on acceptable terms with prospective clinical study sites, the terms of which can be subject to extensive negotiation and may vary significantly among different clinical study sites; ● delays in identifying and recruiting suitable clinical investigators; ● delays in obtaining required IRB approval for each clinical study site or adverse action by one or more IRBs; ● a new safety finding that presents unreasonable risk to clinical study participants; ● a negative finding from an inspection of our clinical research organization (CRO), clinical study operations or study sites; ● the finding that the investigational protocol or plan is deficient to meet its stated objectives; ● delays in identifying, recruiting, and enrolling suitable patients to participate in our clinical studies, and delays caused by patients withdrawing from clinical studies, or failing to return for post- treatment follow- up; ● delays caused by disease epidemics, pandemics, ~~such as COVID- 19,~~ or other health crises; ● difficulty collaborating with patient groups and investigators; ● failure by our CRO or other third parties, or us to adhere to clinical study requirements; ● failure to perform in accordance with FDA' s or any other regulatory authority' s Code of Good Clinical Practice (GCP) requirements, or other regulatory guidelines in other countries; ● occurrence of adverse events associated with the product candidate that are viewed to outweigh its potential benefits; ● changes in regulatory requirements and guidance that require amending or submitting new clinical protocols; ● changes in the standard of care on which a clinical development plan was based, which may require new or additional studies; ● the cost of clinical studies of our product candidates being greater than we anticipate; ● clinical studies of our product candidates producing negative or inconclusive results, which may result in our deciding, or regulators requiring us, to conduct additional clinical studies or abandon product development programs; and ● delays in manufacturing, testing, releasing, validating, or importing / exporting sufficient stable quantities of our product candidates for use in clinical studies or the inability to do any of the foregoing. Any inability to successfully initiate or complete clinical studies could result in additional costs to us or impair our ability to generate revenue. In addition, if we make manufacturing or formulation changes to our product candidates, we may be required to, or we may elect, to conduct additional studies to bridge our modified product candidates to earlier versions. Clinical study delays could also shorten any periods during which our products have patent protection and may allow our competitors to bring products to market before we do, which could impair our ability to successfully commercialize our product candidates and may harm our business and results of operations. Delays in the completion of any clinical study of our product candidates will increase our costs, slow down our product candidate development and approval process and delay, or potentially jeopardize our ability to commence product sales and generate revenue. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical studies may also ultimately lead to the denial of regulatory approval of our product candidates or the termination of such clinical studies prior to their completion, either of which could adversely affect our business. **The FDA may not accept data from Phase 3 clinical trials conducted in foreign locations.** We have conducted ~~,~~ and ~~continue to~~ **may in the future** conduct ~~,~~ portions of our Phase 3 clinical trials outside the United States ~~, and the FDA may not accept data from trials conducted in foreign locations. We have conducted, and we expect to continue to conduct, portions of our Phase 3 clinical trials outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA~~ . For example, the clinical trial must be conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U. S. population, and the data must be applicable to the U. S. population and U. S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials we conduct outside the United States must be representative of the population for which we intend to label the product in the United States. In addition, while Phase 3 clinical trials conducted outside the United States are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U. S. laws and regulations. We cannot assure you that the FDA will accept data from portions of our Phase 3 trials conducted outside the United States. If the FDA does not accept such data from such clinical trials, we would likely need to conduct additional trials, which would be costly and time- consuming and delay or permanently halt our development of simufilam, our lead investigational product. The FDA or other regulatory agencies may put a clinical hold on our clinical studies, which would cause our business to suffer. A clinical hold is an order issued by FDA or another regulatory agency to suspend an ongoing clinical trial, typically due to newly identified deficiencies with, or the need for additional information regarding, the subject study or drug candidate. ~~For example, we are aware that in 2022, FDA placed clinical holds on drug candidates for Alzheimer' s disease from two competitors, Cortexzyme Inc. and Denali Therapeutics Inc.~~ The grounds for imposition of a clinical hold are complex, variable and fact specific. If FDA imposes a clinical hold on ~~us~~ **any of our future clinical studies** , no new patients may be enrolled in the subject study and study patients already in such study may be taken off our drug candidate unless treatment is specifically permitted by FDA in the interest of patient safety. If we are issued a clinical hold, FDA would expect us to address the cited deficiencies or provide the requested additional information, in each case, through the submission of a detailed, written response. A clinical hold would require us to spend significant resources, potentially over an extended period of time, to address the root causes of FDA' s concerns, even if we disagreed with the FDA' s assessment of asserted deficiencies. If we were unable to find and successfully address such root causes or if our response were deemed inadequate to lift the clinical hold, this could adversely affect our business. If we were subjected to a clinical hold that remained in effect for one year or longer, the FDA may consider the IND for the affected product candidate to fall into Inactive Status, which may result in termination of the corresponding clinical program. To the extent we are not successful in lifting any clinical hold that the FDA might impose, our results of operations and business will be materially adversely affected. Even if FDA approves our drugs, physicians and patients may not accept and use them. Acceptance and use of our drugs will depend on a number of factors including: ● when the drug is launched into the market and related competition; ● approved label claims; ● perceptions by members of the healthcare community, including physicians, about the safety, side effects and effectiveness of our drugs; ● perceptions by physicians regarding the cost- benefit of our product candidates; ● published studies demonstrating the cost effectiveness of our

drugs relative to competing products; ● availability of reimbursement for our products from government or healthcare payers; ● effectiveness of marketing and distribution efforts by us and other licensees and distributors. Because we expect to rely on sales generated by our current lead product candidates for substantially all of our revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing. We may not be successful in developing our product candidates in neurodegeneration ~~. In addition to the risks associated with our~~ **or other** ~~Phase 3 clinical trials for~~ **forms** ~~simufilam, SavaDx and our future~~ **of central nervous system disorders. All of the** product candidates in ~~neurodegeneration~~ **our pipeline** are still in development. Such ~~early stage~~ product candidates will take several years to develop and must undergo extensive clinical and scientific validations. Even if we are successful in developing any of our product candidates through clinical and scientific validation, we may not be able to develop a drug or a diagnostic that: ● meets applicable regulatory standards, in a timely manner or at all; ● successfully competes with other technologies and tests; ● avoids infringing the proprietary rights of others; ● is adequately reimbursed by third- party payors; ● can be performed at commercial levels or at reasonable cost; or ● can be successfully marketed. To the extent we are not successful in developing ~~our new~~ product candidates ~~in neurodegeneration~~, our results of operations and business will be materially adversely affected. Interim, " top- line " and preliminary data from our clinical trials that we announce or publish from time to time are likely to change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final dataset. From time to time, we may publish " top- line " or preliminary data from our clinical trials. 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 at the time of its initial release. As a result, the top- line results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Such data from clinical trials may materially change as more study data become available. Preliminary or " top- line " data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, preliminary top- line data should be viewed with caution until the final data is available. Differences between preliminary or top- line data and final data could significantly harm our business prospects and may cause the trading price of our securities to fluctuate significantly. Furthermore, other parties, including regulatory agencies, may not accept or agree with our assumptions, estimates, calculations, conclusions or analyses or may interpret or weigh the importance of data differently than us, which could impact the value of the particular program, the approvability or commercialization of the particular product candidate and our company in general. In addition, the information we choose to publicly disclose regarding a particular study or clinical trial is typically selected from a more extensive amount of available information. You or others may not agree with what we determine is the 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 product candidate or our business. If the preliminary or ~~topline~~ **top- line** data that we report differ from later, final or actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize our product candidates may be harmed, which could harm our business, financial condition, results of operations and prospects. We currently have no in- house capabilities to manufacture or commercialize our product candidates **,** and we rely on third- party commercial drug manufacturers for ~~clinical drug~~ supplies **of simufilam** . If we are unable to develop our own manufacturing, sales, marketing and distribution capabilities, or if we are not successful in contracting with third parties for these services on favorable terms, or at all, our product revenues could be adversely impacted. We rely on various third parties to manufacture, fill, label, store, test and ship our product candidates. We plan to continue to outsource formulation, manufacturing and related activities. These suppliers must comply with cGMP regulations enforced by FDA and other government agencies, and are subject to ongoing periodic unannounced inspection, including preapproval inspections by FDA and corresponding state and foreign government agencies to ensure strict compliance with cGMP and other standards. These manufacturers may subsequently be stopped from producing, manufacturing, filling, labeling, storing, testing and shipping our product candidates due to their non- compliance with federal, state or local regulations. We do not have control over our suppliers' compliance with these regulations and standards and we cannot control decisions by our suppliers that affect their ability or willingness to continue to supply us on acceptable terms, or at all. Disputes **may** ~~in the past have arisen~~ **arise** with ~~some of these~~ third **party service providers** ~~parties with respect to fulfilling certain conditions and obligations. There can be no guarantee that such disputes will not arise again in the future~~, which may lead to termination of an agreement. If an agreement is terminated, we would not be able to commercialize our product candidates until another manufacturer is identified and we have entered into a manufacturing agreement with such manufacturer. We may not be able to replace a commercial supplier on commercially reasonable terms, or at all. Replacing any of our commercial suppliers would be expensive and time consuming. Failure by any of our suppliers to perform as expected could delay or prevent the commercialization or potential regulatory approval of our product candidates for an extended period of time, result in shortages, cost overruns or other problems and would materially harm our business. We currently have no sales, marketing or distribution capabilities. We have not established commercial strategies regarding any of our product candidates. In order to commercialize our products, if any are approved by FDA, we will either have to develop such capabilities internally or collaborate with third parties who can perform these services for us. If we decide to commercialize any of our drugs ourselves, we may not be able to ● hire and retain the necessary experienced personnel; ● build sales, marketing and distribution operations in a cost- effective manner which are capable of successfully launching new drugs; ● obtain access to adequate numbers of physicians to prescribe our products; or ● generate sufficient product revenues. In addition, establishing such operations on our own will take time and involve significant expense. If our commercial operations lack complementary products, we may not be able to compete in a cost- effective manner with competitors with more products to sell. If we engage third- party collaborators to perform any commercial operations, our future revenues may depend significantly upon the performance of those collaborators. If we decide to enter into new co- promotion or

other licensing arrangements with third parties, we may be unable to locate acceptable collaborators because the number of potential collaborators is limited and because of competition from others for similar alliances. Even if we are able to identify one or more acceptable new collaborators, we may not be able to enter into any collaborative arrangements on favorable terms, or at all. In addition, due to the nature of the market for our product candidates, it may be necessary for us to license all or substantially all of our product candidates to a single collaborator, thereby eliminating our opportunity to commercialize these other products independently. If we enter into any such new collaborative arrangements, our revenues are likely to be lower than if we marketed and sold our products ourselves. In addition, any revenues we receive would depend upon our collaborators' efforts which may not be adequate due to lack of attention or resource commitments, management turnover, change of strategic focus, business combinations or other factors outside of our control. Depending upon the terms of our collaboration, the remedies we have against an under- performing collaborator may be limited. If we were to terminate the relationship, it may be difficult or impossible to find a replacement collaborator on acceptable terms, or at all. We rely on third parties to conduct our studies and some aspects of our research, and such third parties may not perform satisfactorily, which could delay or harm our studies, research, and testing. We substantially rely and expect to continue to rely on third parties, such as contract research organizations (CROs), clinical data management organizations, medical institutions, and clinical investigators, to conduct some aspects of our research and preclinical testing and our clinical studies. For example, Pentara Corporation, an independent consulting firm that specializes in complex statistical analysis of clinical trials, has conducted statistical analysis relating to cognition endpoints in our clinical studies. Any of these third parties may terminate their engagements with us or be unable to fulfill their contractual obligations. If we need to enter into alternative arrangements, it will delay our product development activities. Our reliance on these third parties for research and development activities reduces our control over these activities but does not relieve us of our responsibilities. For example, we remain responsible for ensuring that all of our clinical studies are conducted in accordance with the general investigational plan and protocols for the trial. Moreover, FDA requires us to comply with the norms of Good Clinical Practice (GCPs) for conducting, recording, and reporting the results of clinical studies to assure that data and reported results are credible, reproducible, and accurate and that the rights, integrity, and confidentiality of study participants are protected. We also are required to register ongoing clinical studies and post the results of completed clinical studies on a government- sponsored database within certain timeframes. Failure to do so can result in fines, adverse publicity, and civil and criminal sanctions. If our third- party vendors do not successfully carry out their contractual duties, meet expected deadlines, or conduct studies in accordance with regulatory requirements or our stated protocols, we will not be able to obtain, or may be delayed in obtaining, marketing approvals for any product candidates we may develop and will not be able to, or may be delayed in our efforts to, successfully commercialize our product candidates. For example, one of our vendors failed to fully comply with certain Good Laboratory Practice (GLP) norms in its research facility, which required us to repeat a lab study at a different research site. We also rely on other third parties to label, store and distribute drug supplies for our clinical studies. Any performance failure on the part of our distributors, including with the shipment of any drug supplies, could delay clinical development or marketing approval of any product candidates we may develop or commercialization of our product candidates, producing additional losses and depriving us of potential product revenue. We may not be successful in our efforts to expand our technology or product candidates in other indications. Our drug development strategy ~~is to~~ **has been focused on** clinically **testing** ~~test and seek regulatory approval for~~ our product candidates in Alzheimer' s disease ~~dementia~~, our primary indication. We may expand our research efforts outside of this primary indication and into other areas of clinical medicine based on ~~genetic, biological~~ **a variety of factors.** ~~or~~ **For** ~~mechanistic overlap~~ **example, we plan to conduct exploratory preclinical studies in collaboration** with the ~~primary indication~~ **TSCA to better understand simufilam' s potential as a treatment for seizures in TSC** . Conducting clinical studies for additional indications for our product candidates will require substantial technical, financial and human resources and is prone to the inherent risks of failure in drug development. We cannot provide any assurance that we will be successful in our effort to expand our technology or our product candidates in additional indications ~~, even if we obtain approval for our product candidate in Alzheimer' s disease~~ . If we fail to successfully identify and develop additional product candidates, our commercial opportunity will be limited ~~to Alzheimer' s disease or other neurodegenerations~~ . Identifying, developing, obtaining regulatory approval for, and commercializing additional product candidates requires substantial expertise and funding and is prone to the risks of failure inherent in drug development. We cannot provide any assurance that we will be able to successfully identify or acquire additional product candidates, advance any additional product candidates through the development process, or assemble sufficient resources to identify, acquire, or develop additional product candidates. If we are unable to successfully identify, acquire, develop, and commercialize additional product candidates, our commercial opportunity may be limited. We have never obtained FDA approval for a diagnostic test and we may not be able to secure such approval in a timely manner or at all. We are developing an investigational blood- based diagnostic test for Alzheimer' s disease, called SavaDx, which will require FDA approval prior to commercialization. Our diagnostic product candidate, marketing, sales and development activities and manufacturing processes are subject to extensive and rigorous regulation by FDA pursuant to the FDCA, by comparable agencies in foreign countries, and by other regulatory agencies and governing bodies. Under the FDCA, a diagnostic must receive FDA clearance or approval before it can be commercially marketed in the United States. The process of obtaining marketing approval or clearance from FDA or by comparable agencies in foreign countries for new products could: ● take a significant period of time; ● require the expenditure of substantial resources; ● involve rigorous preclinical testing, as well as increased post- market surveillance; ● require changes to products; and ● result in limitations on the indicated uses of products. If we do not compete effectively with scientific and commercial competitors, we may not be able to successfully develop our diagnostic test for Alzheimer' s disease. The field of clinical laboratory testing is highly competitive. Diagnostic tests are characterized by rapid technological change. Our competitors in the United States and abroad are numerous and include, among others, major diagnostic companies, reference laboratories, molecular diagnostic firms, universities and other research institutions. Most of our potential competitors have considerably

greater financial, technical, marketing and other resources than we do, which may allow these competitors to discover important biological markers and determine their function before we do. We could be adversely affected if we do not discover proteins or biomarkers and characterize their function, develop diagnostic and pharmaceutical and clinical services based on these discoveries, obtain required regulatory and other approvals and launch these tests and their related services before our competitors. We also expect to encounter significant competition with respect to any diagnostic tests that we may develop or commercialize. Those companies that bring to market new diagnostic tests before we do may achieve a significant competitive advantage in marketing and commercializing their tests. We may not be able to develop additional diagnostic tests successfully and we may not obtain or enforce patents, if any, covering these tests that provide protection against our competitors. Moreover, our competitors may succeed in developing diagnostic tests that circumvent our technologies or tests. Furthermore, our competitors may succeed in developing technologies or tests that are more effective or less costly than those developed by us or that would render our technologies or tests less competitive or obsolete. We expect competition to intensify in the fields in which we are involved as technical advances in these fields occur and become more widely known and changes in intellectual property laws generate challenges to our intellectual property position. We will need to ~~develop our own proprietary antibodies or~~ find alternative approaches that do not involve antibodies to advance our SavaDx and our diagnostic program. To date, most of our tests with SavaDx have relied on the use of commercially available antibodies, which are complex molecules that can recognize and bind to an intended protein. Commercially available antibodies can present technical challenges, such as improper validation, significant batch- to- batch variations or inconsistent storage, any of which can jeopardize our studies and experiments. ~~We~~ **Hence, we** are ~~also~~ evaluating an alternative approach to detect Alzheimer' s disease using mass spectrometry to detect FLNA, i. e., without the use of antibodies. The complexity of such an alternative approach also gives rise to many technical issues that are challenging to solve. We cannot be certain that we will be able to successfully complete the development of a detection system for Alzheimer' s disease that does or does not involve antibodies. Our Phase 2 clinical studies with simufilam ~~in patients with Alzheimer' s disease~~ are generally not designed to show a statistically meaningful difference in cognition or other health functions between those patients who receive placebo and those who receive drug. Clinical research data is often analyzed with statistical probability (p- value) to address the question of whether a clinical observation is related to a treatment effect, a random effect or something else. This, in turn, requires a clinical study to incorporate a sufficiently large sample patient population to infer the appropriate statistical analysis. By design, our Phase 2 clinical studies with simufilam generally do not include a sufficiently large patient population to generate statistical probability on measures of cognition or other health functions. This feature may make it difficult for investors to properly interpret whether clinical observations in those Phase 2 studies with simufilam are important or meaningful. Conversely, our clinical studies may generate statistically significant data (i. e., $p < 0.05$) on exploratory biomarkers, or other endpoints, that have unknown or no clinical importance. In general, the distinction between statistically significant data and clinically meaningful data is a complex area of research that continues to evolve and may be subject to differences of opinion among scientists, clinicians, biostatisticians and other professionals, as well as among government regulators. ~~In~~ **To the extent that** our open- label study **suggested** ~~, we observed apparent~~ differences in treatment effects by stage of disease ~~. These~~ **, such** observations may or may not replicate in any of our subsequent clinical studies. Alzheimer' s dementia is a progressive, degenerate disease. Severity of disease is typically assessed by stage of disease progression, a continuum that ranges from, approximately, mild cognitive impairment (MCI), to early stage, to mild, to moderate and finally to severe disease. Over time, cognition progressively worsens in the mild- to- moderate stages of Alzheimer' s as the disease takes its toll. However, we do not have a clear understanding of how our drug candidate simufilam may impact patients by stage of disease, if at all. For example, ~~in~~ **to the extent that** our open- label and small placebo- controlled studies **suggested** ~~, we observed~~ apparent differences in treatment effects by stage of disease ~~. While we believe our data in mild patients may emphasize the importance of treating patients early in the disease~~ , such observations ~~may or~~ may not replicate in any of our subsequent clinical studies. **Our** ~~We expect to rely on~~ clinical ~~results generated predominately,~~ **studies may fail to demonstrate substantial evidence of the safety and efficacy of** ~~or~~ **our** ~~even solely,~~ **product candidates and may suffer** from **improper** ~~patients with mild Alzheimer' s disease to show evidence of efficacy in our~~ **or inadequate study design** ~~Phase 3 clinical trials, if any. Our reliance on patients with mild disease may narrow our~~ **or enrollment criteria** ~~ability to broadly market simufilam to the Alzheimer' s disease community~~ , ~~if~~ **which would prevent, delay,** ~~our~~ **or** ~~drug candidate receives~~ **limit the scope of** regulatory approval ~~. Our Phase 3 trials have randomized a total of approximately 1, 900 patients with mild to moderate stages of Alzheimer' s disease at baseline (MMSE 16- 27). Approximately 70 % of these patients are diagnosed with mild Alzheimer' s disease (MMSE 20- 27). Since the distribution of patients randomized into these trials is numerically skewed towards mild patients, we expect to rely predominantly, or even solely, on outcomes from mild patients to show evidence of drug efficacy, if any, in our Phase 3 trials. Our reliance on mild Alzheimer' s patients to show evidence of drug efficacy in our Phase 3 trials may not allow us to meet the regulatory standards required to gain a broad label indication in Alzheimer' s disease,~~ and **commercialization** ~~this may limit our ability to broadly market simufilam to the Alzheimer' s disease community, if our drug candidate receives regulatory approval and becomes commercially available. We may encounter difficulties keeping patients enrolled in our Phase 3 clinical studies, and our clinical development activities could thereby be delayed or otherwise adversely affected. The successful completion of clinical studies in accordance with their protocols depends, among other things, on our ability to keep patients enrolled in our Phase 3 studies until study conclusion. Patients who are enrolled in our Phase 3 studies may terminate their participation for a many reasons, including: ● moving away from a clinical site; ● inability to keep appointments due to loss of mobility or caregiver; ● perceptions as to the efficacy of treatment, or lack thereof, including those who are randomized to placebo; ● side- effects associated with treatment; ● loss of interest or motivation to continue participation in clinical research; ● patient non- compliance or protocol deviations; ● interest in other available therapies and product candidates; ● withdrawal of patient consents; and ● the emergence of severe or debilitating health issues unrelated to study participation, such as a fall resulting in a fractured hip~~ . Before obtaining regulatory approvals

for any of our product candidates, we must demonstrate through lengthy, complex, and expensive preclinical experiments and clinical studies that our product candidates are both safe and effective for use in an intended population. Each product candidate must demonstrate an adequate risk versus benefit profile in its intended patient population and for its intended use, as determined by the FDA in the United States. New drug discovery, development and commercialization involves a high degree of risk. The process is expensive and complex and can take many years to complete, and its outcome is inherently uncertain. It can take over 10 to 15 years and cost over $ 1 to $ 2 billion for each new drug candidate to achieve regulatory approval. Only a small number of research and development programs achieve regulatory approval and subsequent commercialization of a drug product. We believe that in recent decades about 90 to 95 % of novel drug candidates under development by the biopharmaceutical industry have failed to achieve regulatory approval and subsequent commercialization. Failure can occur at any time during the drug discovery and development process and such failures may be due to lack of clinical efficacy, adverse safety profile, regulatory hurdles, excessive costs, lack of perceived market opportunity, lack of resources, insufficient reimbursement from insurers, inability to compete or for other reasons. Many biopharmaceutical companies have suffered significant setbacks in Phase 3 clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Seasoned professionals with a prior track record of innovation in drug discovery and development, as well as substantial business expertise, routinely fail to achieve regulatory approval of new product candidates. The results of our preclinical studies with our product candidates may not be predictive of the results of early- stage or later- stage clinical studies, and results of early clinical studies of our product candidates may not be predictive of the results of later- stage clinical studies. The results of clinical studies in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, and other clinical study protocols and the rate of dropout among clinical study participants. ~~Our open- label extension study may also extend the timing and overall cost of our clinical development program substantially.~~ Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical studies. We may suffer significant setbacks in ~~our ongoing~~ Phase 3 clinical studies due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier studies. **For example, our first Phase 3 trial in Alzheimer' s disease did not meet each of the pre- specified co- primary, secondary and exploratory biomarker endpoints.** Clinical trials in ~~neurodegenerative diseases~~ **central nervous system disorders** , including Alzheimer' s disease, have much higher historically failure rates than in many other disease areas. Most new product candidates for ~~neurodegeneration~~ **central nervous system disorders** that begin clinical studies are never approved by regulatory authorities for commercialization. **Our clinical trials may suffer from improper or inadequate study design or enrollment criteria.** We have limited experience in designing clinical studies in neurodegeneration and may be unable to design and execute a clinical study to support marketing approval. We cannot be certain that our current clinical studies or any other future clinical studies will be successful. Additionally, any safety concerns observed in any one of our clinical studies in our targeted indications could limit the prospects for regulatory approval of our product candidates in those and other indications, which could have a material adverse effect on our business, financial condition, and results of operations. In addition, even if such clinical studies are successfully completed, we cannot guarantee that FDA or foreign regulatory authorities will interpret the results as we do, and more studies could be required before we submit our product candidates for approval. To the extent that the results of the studies are not satisfactory to FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional studies in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit its commercial potential. ~~If our drug candidate causes or contributes to a death or a serious injury before or after approval, we will be subject to medical reporting regulations, which can result in voluntary corrective actions or agency enforcement actions. Our drug candidate in Alzheimer' s disease is aimed at elderly patients with dementia, some of whom may be frail due to advanced age or underlying health issues. Under FDA medical reporting regulations, we are required to report to the FDA information that our drug candidate has or may have caused or contributed to a death or serious injury. Any such serious adverse event involving our drug could result in future FDA action, such as an inspection, enforcement action or warning, or in more serious cases, a complete shutdown of our clinical program. In the context of our ongoing clinical trials, we report adverse events to the FDA in accordance with applicable national and local regulations. Any corrective action, whether voluntary or involuntary, and either pre- or post- market, needed to address any serious adverse events will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.~~ The market opportunities for simufilam ~~and SavaDx~~ , if approved, may be smaller than we anticipate. If our clinical development programs succeed **with respect to simufilam for a particular indication** , we **would** expect to seek regulatory approval of simufilam ~~and SavaDx~~ for **such indication. Projections that we calculate as to the number of** patients with ~~Alzheimer' s disease. Our projections of~~ the **indications that we are studying are** ~~number of patients with Alzheimer' s disease is~~ based on our beliefs and estimates **,** ~~. These estimates have been~~ derived from a variety of outside sources, including scientific literature, patient foundations and market research ~~, and~~ **. Our projections** may prove to be incorrect. The actual number of patients **for a particular indication** may turn out to be lower than expected. Additionally, the potential patient population for our current programs or future product candidates may be limited. Even if we obtain regulatory approval and capture significant market share for any product candidate, the potential target populations may be smaller than anticipated, and we may never achieve profitability without obtaining marketing approval for additional indications. We face significant competition in an environment of rapid technological and scientific change, and there is a possibility that additional competitors may achieve regulatory approval before us or develop therapies that are safer, more advanced, or more effective

than ours, any of which may harm our business operations. Drug discovery and development is highly competitive. Moreover, the ~~neurodegenerative~~ **central nervous system disorders** field is characterized by intense and increasing competition, and a strong emphasis on intellectual property. We may face competition with respect to any of our product candidates that we seek to develop or commercialize in the future from major pharmaceutical companies, specialty pharmaceutical companies, and biotechnology companies worldwide. Potential competitors also include academic institutions, government agencies, and other public and private research organizations that conduct research, seek patent protection, and establish collaborative arrangements for research, development, manufacturing, and commercialization. ~~In addition to Biogen, Eisai and Eli Lilly, several~~ **Several** pharmaceutical and biotechnology companies are currently pursuing the development of products for the treatment of ~~neurodegenerative diseases~~ **central nervous system disorders** , including Alzheimer' s disease **and TSC- related epilepsy** . Many of these current or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical studies, obtaining regulatory approvals, and marketing approved products than we do. Our commercial opportunity could be reduced or eliminated if other competitors develop and commercialize products that are safer, are more effective, have fewer or less severe side effects, are more convenient, achieve greater acceptance among physicians and patients, or are less expensive than any products that we may develop. Furthermore, currently approved products could be discovered to have application for treatment of neurodegenerative disease indications, which could give such products significant advantages over any of our product candidates. Competitors ~~other than Biogen, Eisai and Eli Lilly~~ may also obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. Additionally, products or technologies developed by our competitors may render our potential product candidates uneconomical or obsolete, and we may not be successful in marketing any product candidates we may develop against competitors. In addition, we could face litigation or other proceedings with respect to the scope, ownership, validity, and / or enforceability of our patents relating to our competitors' products and our competitors may allege that our products infringe, misappropriate, or otherwise violate their intellectual property. The availability of our competitors' products could limit the demand, and the price we are able to charge, for any products that we may develop and commercialize. We are, and may in the future be, subject to various investigations and legal proceedings. In recent years, there has been a trend of increasing government investigations, legal proceedings and law enforcement activities against companies, executives and others operating in our industry, including those arising from whistleblower programs operated by the SEC and DOJ and the qui tam provisions of the False Claims Act. We are currently managing inquiries from U. S. government agencies, as well as civil claims under federal and state laws, relating to and / or arising out of research and development of our product candidates, including grant applications, securities disclosures and other aspects of our business. For additional information regarding legal proceedings, see" ~~Item 8.~~ **Notes to Consolidated** Financial ~~Information~~ **Statements** — **Contingencies** ~~8. A. Consolidated Statements and Other Financial Information — Legal Proceedings~~ ". New claims or inquiries may arise in the future. In response to government document requests and other claims asserted against us, we established a comprehensive document retention policy that strictly governs how we handle, store and protect our documents and data. Failure to comply with our document retention policy would expose us to risk of enforcement actions and penalties under applicable laws. Legal proceedings are inherently unpredictable, and large judgments or penalties sometimes occur. As a consequence, we may in the future incur judgments or penalties that could involve large cash payments, including the potential repayment of amounts allegedly obtained improperly and other penalties, including enhanced damages. **For example, the Company paid a civil monetary penalty of $ 40 million in November 2024 as part of a settlement with the SEC resolving the SEC investigation of the Company' s disclosures regarding its Phase 2b Study and related matters.** While we maintain insurance coverage for certain types of claims, such insurance coverage may be insufficient to cover all losses or all types of claims that may arise. In addition, such proceedings against us or against third parties with whom we collaborate or otherwise do business may affect our reputation, inhibit our ability to raise fund in the capital markets, create a risk of potential exclusion from government reimbursement or grant programs and may lead to additional civil litigation. Even meritless claims could subject us to adverse publicity, hinder us from securing insurance coverage in the future or require us to incur significant legal costs. As a result, having taken into account all relevant factors, we may in the future enter into settlements of such claims without bringing them to final legal adjudication by courts or other such bodies, despite having potentially significant defenses against them, in order to limit the risks they pose to our business and reputation. Such settlements may require us to pay significant sums of money and to enter into corporate integrity or similar agreements intended to regulate company behavior for a period of years, which can be costly to operate under. As a result, significant claims or legal proceedings to which we are a party, any judgments or settlements against us or involving third parties associated with us relating to such claims or proceedings, and any accruals that we may take with respect to potential judgments or settlements, could have a material adverse impact on our business, financial condition or results of operations, as well as on our reputation. Additional future litigation involving us could be costly and time- consuming to defend. Innovative drug development is highly litigious, and we may, from time to time, become subject to or involved in additional legal proceedings, claims and allegations that arise in the ordinary course of business or pursuant to governmental or regulatory enforcement activity. Regardless of merit, any lawsuits against or involving us, individually or in the aggregate, may have a material adverse effect on our business, financial condition, results of operations or cash flows. In addition, any litigation to which we subsequently become a party might result in substantial costs and divert management' s attention, time and resources, which might seriously harm our business, financial condition, results of operations and cash flows. Our insurance policies might not cover such claims, might not provide sufficient payments to cover all of the costs to resolve one or more such claims, and might not continue to be available on terms acceptable to us. In particular, any claim could result in potential liability for us if the claim is outside the scope of the indemnification agreement we have with our third- party partners, or our third- party partners do not abide by the indemnification agreement as required, or the liability exceeds the amount of any

applicable indemnification limits or available insurance coverage. A claim brought against us that is uninsured or underinsured could result in unanticipated costs and could have a material adverse effect on our financial condition, results of operations, cash flows or reputation **. If we are ultimately unable to file for and obtain regulatory approval for our product candidates, we will be unable to generate product revenue, and our business will be substantially harmed** . The time required to obtain approval by FDA and comparable foreign regulatory authorities is unpredictable, typically takes many years following the commencement of clinical studies, and depends upon numerous factors, including the type, complexity, and novelty of the product candidates involved. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate' s clinical development and may vary among jurisdictions, which may cause delays in the approval or the decision not to approve an application. Regulatory authorities have substantial discretion in the approval process and may refuse to accept any application or may decide that our data are insufficient for approval and require additional preclinical, clinical, or other studies. We have not obtained regulatory approval for any product candidate ~~, including our product candidates aimed at Alzheimer' s disease,~~ and it is possible that none of our existing product candidates or any product candidates we may seek to develop in the future will ever obtain regulatory approval. Applications for our product candidates could fail to receive regulatory approval in an initial or subsequent indication for many reasons, including but not limited to the following: ● FDA or comparable foreign regulatory authorities may disagree with the design, implementation, or results of our clinical studies; ● FDA or comparable foreign regulatory authorities may determine that our product candidates are not safe and effective, only moderately effective or have undesirable or unintended side effects, toxicities, or other characteristics that preclude our obtaining marketing approval or prevent or limit commercial use; ● the population studied in the clinical program may not be sufficiently broad or representative to assure efficacy and safety in the full population for which we seek approval; ● we may be unable to demonstrate to FDA or comparable foreign regulatory authorities that a product candidate' s risk- benefit ratio when compared to the standard of care is acceptable; ● FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical studies; ● the data collected from clinical studies of our product candidates may not be sufficient to support the submission of a new drug application (NDA), or other submission or to obtain regulatory approval in the United States or elsewhere; ● FDA or comparable foreign regulatory authorities may fail to approve the manufacturing processes, test procedures, and specifications, or facilities of third- party manufacturers with which we contract for clinical and commercial supplies; and ● the approval policies or regulations of FDA or comparable foreign regulatory authorities may significantly change in a manner rendering our clinical data insufficient for approval. This lengthy approval process, as well as the unpredictability of the results of clinical studies, may result in our failing to obtain regulatory approval to market any of our product candidates, which would significantly harm our business, results of operations, and growth prospects. The commercial success of our product candidates will depend upon our ability to obtain FDA- approved labeling effectively describing their features. If a product receives regulatory approval, the approval may be significantly limited to specific disease stages, patient populations and dosages, or the indications for use may otherwise be limited, which could restrict the availability of the product. Further, the FDA may require that certain contraindications, warnings or precautions be included in the product labeling or may condition the approval of the NDA on other changes to the proposed labeling or a commitment to conduct one or more post- market studies or clinical trials. For example, the FDA may require Phase 4 testing which involves clinical trials designed to further assess a drug' s safety and effectiveness. Our failure to achieve FDA approval of product labeling containing appropriate information will prevent us from advertising and promoting the key features of our product candidates in order to differentiate them from other similar products. On the other hand, limitations required by the FDA for the product labeling of our product candidates may restrict the patient populations to which our product candidate is available. Either of these results would make our products less competitive in the market the commercial value of the product. Our employees, independent contractors, consultants, commercial partners, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of fraud, misconduct, or other illegal activity by our employees, independent contractors, consultants, commercial partners, and vendors. Misconduct by these parties could include intentional, reckless, and negligent conduct that fails to: ● comply with the laws of FDA and other comparable foreign regulatory authorities; ● provide true, complete, and accurate information to FDA and other comparable foreign regulatory authorities; ● comply with manufacturing standards we have established; ● comply with healthcare fraud and abuse laws in the U. S. and similar foreign fraudulent misconduct laws; ● report financial or clinical information or data accurately or to disclose unauthorized activities to us; or ● otherwise comply with applicable criminal, civil or regulatory laws governing their conduct. **For example, on June 28, 2024, the DOJ announced that a federal grand jury in the U. S. District Court for the District of Maryland returned an indictment of Dr. Hoau- Yan Wang, a former scientific collaborator and advisor to Cassava. The indictment alleges that Dr. Wang caused Cassava to submit grant applications to NIH that contained false and fraudulent representations about his research. See " — 2024 Non- Product Development Business Developments — Indictment of Hoau- Yan Wang. "** Activities subject to laws also involve the improper use of information obtained in the course of patient recruitment for clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. Further, it is not always possible to identify and deter misconduct by employees and 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 comply with such laws. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions. We are obligated to comply with the laws of all countries and jurisdictions in which we operate. These laws cover an extremely wide and growing range of activities. Such legal requirements can vary from country to country, and new requirements may be imposed on us from time to time as government and public expectations regarding acceptable corporate behavior change, and enforcement authorities modify interpretations of legal and regulatory

provisions and change enforcement priorities. In addition, we rely on numerous associates, independent contractors, consultants, commercial partners and vendors who may put our reputation, business and operations at risk of material impairment if they engage, or are alleged to engage, in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, in violation of such laws and public expectations. The laws and regulations that govern our operations include, among others: ● the Clinical Laboratory Improvement Amendments (CLIA) of 1988, which are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States, requires that laboratories obtain certification from the federal government, and state licensure laws; ● FDA laws and regulations, including those relating to off-label marketing; ● the Health Insurance Portability and Accountability Act (HIPAA), which imposes comprehensive federal standards with respect to the privacy and security of protected health information and requirements for the use of certain standardized electronic transactions, including penalties for violators, enforcement authority to state attorneys general and requirements for breach notification; ● state laws regulating testing and protecting the privacy of test results, as well as state laws protecting the privacy and security of health information and personal data and mandating reporting of breaches to affected individuals and state regulators; ● the federal anti- kickback law, or the Anti- Kickback Statute, which prohibits knowingly and willfully offering, paying, soliciting, receiving, or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing, arranging for, or recommending of an item or service that is reimbursable, in whole or in part, by a federal health care program; ● the federal False Claims Act (FCA), which imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment to the federal government and which, under its qui tam provisions, allows private litigants (~~called "~~ relators ~~"~~) to file claims under seal on behalf of the government and to receive a percentage of recoveries obtained as a result; ● the federal Civil Monetary Penalties Law, which prohibits, among other things, the offering or transfer of remuneration to a Medicare or state health care program beneficiary if the person knows or should know it is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies; ● other federal and state fraud and abuse laws, such as anti- kickback laws, prohibitions on self- referral, and false claims acts, which may extend to services reimbursable by any third- party payor, including private insurers; ● the Foreign Corrupt Practices Act (FCPA) and other worldwide anti- bribery laws, including those that prohibit companies and their intermediaries from making improper payments to government officials or other third parties for the purpose of obtaining or retaining business, and laws that prohibit commercial bribery; ● import, export control and economic sanctions laws and regulations in the U. S. and elsewhere; ● Federal securities laws, including provisions of the Exchange Act and Dodd- Frank Act under which whistleblowers that report alleged violations of wrongdoing can obtain up to 30 % of related recoveries; ● the federal Physician Payments Sunshine Act, which requires manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and ownership or investment interests held by physicians and their immediate family members; ● section 216 of the federal Protecting Access to Medicare Act of 2014 (PAMA), which requires applicable laboratories to report private payer data in a timely and accurate manner every three years (and in some cases annually); ● state laws that impose reporting and other compliance- related requirements; and ● similar foreign laws and regulations that will apply to us in foreign countries in which we may choose to operate in the future. Government agencies, professional and medical societies, and other groups may establish usage guidelines that apply to our product candidates. These guidelines could address such matters as usage and dose, among other factors. Application of such guidelines could limit the clinical use or commercial appeal of our product candidates. Our product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential, or result in significant negative consequences. During the conduct of clinical trials, study participants report changes in their health to their doctor, including illnesses, injuries and discomforts. Often, it is not possible to determine whether our product candidate caused these conditions. Regulatory authorities may draw different conclusions and may require us to pause our clinical trials or require additional testing to confirm these determinations, if they occur. In addition, we have not yet completed long- term safety studies with simufilam to determine if this product candidate is safe for humans. Adverse events or other undesirable side effects caused by simufilam could cause us or regulatory authorities to interrupt, delay, or halt clinical studies and could result in a more restrictive label or the delay or denial of regulatory approval by FDA or other comparable foreign regulatory authorities. Drug- related side effects could affect patient recruitment, the ability of enrolled patients to complete the study, and / or result in potential claims. We may be subject to legal liability associated with clinical trials. Our business requires us to engage in the conduct of clinical studies in human volunteers and in patients in the United States and abroad. There are circumstances under which a participant in one of our clinical trials could impose liability on us. For example, a clinical investigator who is a participant in one of our studies may intentionally or unintentionally deviate from a clinical protocol and cause harm to a clinical trial participant, or a clinical trial participant may seek to compel us to continue to supply drug to them after the completion of a study but prior to FDA approval. Claims may be brought against us for negligence, breach of contract, harm, injury or death, or other legal theories based on the nature of a study. Clinical trial liability is a complex and somewhat unsettled area of law and may vary by state and by country where we conduct clinical studies. Furthermore, claims may be brought against us by a clinical investigator, a clinical trial participant, or another party associated with a clinical study, long after the completion of a clinical study. Defense of such actions is a fact- intensive process that could be costly and involve significant time and attention of our management and other resources, may result in monetary liabilities or penalties, and may require us to change our business in an adverse manner. Our insurance policies may be inadequate and potentially expose us to unrecoverable risks. Although we maintain product liability insurance coverage, such insurance may not be adequate to cover all liabilities that we may incur. We anticipate that we may need to increase our insurance coverage each time we commence a clinical trial and if we successfully commercialize any product candidate. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable

risks that we identify; however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage and insurers may not respond as we intend to cover insurable events that may occur ~~. We do not carry a separate cybersecurity commercial insurance policy covering the potential financial losses that may occur in the event we experience a cybersecurity incident~~ . Conditions in the insurance markets relating to nearly all areas of traditional corporate insurance change rapidly and may result in higher premium costs, higher policy deductibles and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability. We are and will be required to maintain product liability insurance pursuant to certain of our development and commercialization agreements. We may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. A successful product liability claim or series of claims brought against us could adversely affect our results of operations, business, and reputation. In addition, regardless of merit or eventual outcome, product liability claims may result in impairment of our business reputation, withdrawal of clinical study participants, costs due to related litigation, distraction of management' s attention from our primary business, initiation of investigations by regulators, substantial monetary awards to patients or other claimants, the inability to commercialize our product candidates, and decreased demand for our product candidates, if approved for commercial sale. If our product candidates receive regulatory approval, we and our collaborators will be subject to ongoing FDA obligations and continued regulatory review, such as continued safety reporting requirements, and we and our collaborators may also be subject to additional FDA post- marketing obligations or new regulations, all of which may result in significant expense and limit our and our collaborators' ability to commercialize our potential drugs. Any regulatory approvals that our product candidates receive may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for potentially costly post- marketing follow- up studies. In addition, if FDA approves any of our product candidates, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record keeping for the drug will be subject to extensive regulatory requirements. The subsequent discovery of previously unknown problems with the drug, including but not limited to adverse events of unanticipated severity or frequency, or the discovery that adverse events previously observed in preclinical research or clinical studies that were believed to be minor actually constitute much more serious problems, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market. The FDA' s policies may change, and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the U. S. or abroad. If we are not able to maintain regulatory compliance, we may be subject to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Any of these events could prevent us from marketing our products and our business could suffer. Enacted and future legislation may increase the difficulty and cost for us to commercialize our product candidates and may reduce the prices we are able to obtain for our product candidates. Legislative and regulatory changes and future changes regarding the healthcare system could prevent or delay marketing approval of our product candidates, restrict or regulate post- approval activities or affect our ability to profitably sell any product candidates for which we obtain marketing approval. In the U. S., the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the Medicare Modernization Act) established the Medicare Part D program and provided authority for limiting the number of drugs that will be covered in any therapeutic class thereunder. The Medicare Modernization Act, including its cost reduction initiatives, could limit the coverage and reimbursement rate that we receive for any of our approved products. Private payors may follow Medicare coverage policies and payment limitations in setting their own reimbursement rates resulting in similar limits in payments from private payors. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the Affordable Care Act, among other things, imposes a significant annual fee on companies that manufacture or import branded prescription product candidates. It also contains substantial provisions intended to, among other things, broaden access to health insurance, reduce or constrain the growth of health care spending, enhance remedies against healthcare fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, and impose additional health policy reforms, any of which could have a material adverse effect on our business. A significant number of provisions are not yet, or have only recently become, effective, but the Affordable Care Act may result in downward pressure on pharmaceutical pricing, especially under the Medicare program, and may also increase our regulatory burdens and operating costs. The Affordable Care Act, as well as other healthcare reform measures that have been and may be adopted in the future, may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved product, and could seriously harm our future revenues. 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 compromise our ability to generate revenue, attain profitability or commercialize our products. The Affordable Care Act is a highly complex piece of legislation that continues to evolve. We do not and cannot understand or anticipate the full impact and potential implications of the Affordable Care Act on our business or on our drugs. The purported goal of the Inflation Reduction Act (IRA) of 2022 is to lower healthcare costs for Americans, and includes several provisions aimed at reducing drug spending and increasing access to pharmaceuticals. Specifically, the IRA introduces drug- price negotiations by requiring the federal government to negotiate " maximum fair prices " with drug manufacturers for certain brand- name, single- source drugs covered under Medicare Part B and Part D. In addition, the IRA penalizes price increases and expands required discounts on branded, single- source drugs. The IRA is a highly complex piece of legislation that continues to evolve. We do not and cannot understand or anticipate the full impact and potential implications of the IRA on our business or on our drugs, however, we currently believe the IRA may reduce the prices we are able to obtain for our product candidates, if approved in the United States. Our relationships with customers and payors will be subject to applicable anti- kickback, fraud and abuse, transparency, and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, exclusion from government healthcare programs,

contractual damages, reputational harm, administrative burdens, and diminished profits and future earnings. Healthcare providers, physicians and payors play a primary role in the recommendation and prescription of any product candidates for which we may obtain marketing approval. Our current or future arrangements with payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute any product candidates for which we may obtain marketing approval. Even though we do not and will not control referrals of healthcare services or bill directly to Medicare, Medicaid or other third- party payors, federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business. Restrictions under applicable federal, state and foreign healthcare laws and regulations may affect our ability to operate and expose us to areas of risk, including: ● the federal Anti- Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federal and state healthcare programs such as Medicare and Medicaid. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation; ● the FCA, which imposes criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA; ● HIPAA, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters. Similar to the federal Anti- Kickback Statute, a person or entity does not need to have actual knowledge of the statute to defraud any healthcare benefit program or specific intent to violate it in order to have committed a violation; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and its implementing regulations, which also imposes obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information; ● federal laws requiring drug manufacturers to report information related to payments and other transfers of value made to physicians and other healthcare providers, as well as ownership or investment interests held by physicians and their immediate family members, including under the federal Open Payments program, commonly known as the Sunshine Act, as well as other state and foreign laws regulating marketing activities; and ● state and foreign equivalents of each of the above laws, including 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 payors, including private insurers; state laws which require pharmaceutical companies to comply with the pharmaceutical industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restricting payments that may be made to healthcare providers; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts. Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. Nonetheless, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from participation in government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If we are unable to obtain and maintain sufficient patent protection for any product candidates, our competitors could develop and commercialize products similar or identical to ours, and our ability to successfully commercialize any product candidates we may develop may be adversely affected. Our success depends in large part on our ability to obtain and maintain patent protection in the U. S. and other countries with respect to our proprietary product candidates and other technologies we may develop. We seek to protect our proprietary position by filing patent applications in the U. S. and abroad relating to our core programs and product candidates, as well as other technologies that are important to our business. Given that our product candidates are in early or clinical stages of development, our intellectual property portfolio with respect to certain aspects of our product candidates is also at an early stage. We have filed or intend to file patent applications on aspects of our technology and core product candidates; however, there can be no assurance that any such patent applications will issue as granted patents. Furthermore, in some cases, we ~~have~~ **intend to** ~~filed~~ **file** only provisional patent applications on certain aspects of our technology and product candidates and each of these provisional patent applications is not eligible to become an issued patent until, among other things, we file a non- provisional patent application within 12 months of the filing date of the applicable provisional patent application. Any failure to file a non- provisional patent application within this timeline could cause us to lose the ability to obtain patent protection for the inventions disclosed in the associated provisional patent applications. Furthermore, in some cases, we may not be able to obtain issued claims covering compositions relating to our core programs and product candidates, as well as other technologies that are important to our business, and instead may need to rely on filing patent applications with claims covering a method of use and / or method of manufacture for protection of such core programs, product candidates, and other technologies. There can be no assurance that any such patent applications will issue as granted patents, and even if they do issue, such patent claims may be insufficient to prevent third parties, such as our competitors, from utilizing our technology. Any failure to obtain or maintain patent protection with respect to our core programs and product candidates could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. U. S. intellectual

property rights around diagnostic methods is a complex, evolving area of law and effective patent claims may not be available to us for our investigational diagnostic product candidate, SavaDx, in the United States. The legal system for intellectual property around diagnostic methods is highly complex, remains uncertain and continues to evolve. In the U. S., patent courts have struggled to define a clear means of patent eligibility for modern age diagnostics. Case law interpretations from the U. S. Supreme Court have left certain important scientific advances in the area of diagnostics without effective patent claims. In 2012, the Supreme Court held that a simple process involving correlations between blood test results and patient health is not eligible for patent claims because such processes incorporate " laws of nature ". Since then, different outcomes from different courts, including Federal Circuit, District Court and Patent Trial and Appeal Board decisions, have continued to create a sometimes vague or conflicting legal framework for determining the eligibility of patent claims for diagnostic methods. As a result, we cannot be certain how SavaDx fits into the current U. S. legal framework for obtaining effective patent protection. We currently have no U. S. patents ~~or patent applications~~ with respect to SavaDx, and we believe it may be protected in the United States only by trade secrets, know- how and other proprietary rights technology. Furthermore, claims for diagnostic methods can be complicated to enforce. For patent infringement to occur with a protected diagnostic, the patented method must generally either be performed by one person in its entirety or performed by multiple parties all under the control or direction of a single party. Accordingly, even if effective patent claims are issued for SavaDx, it may be impractical, impossible or even undesirable to enforce potential infringement claims. If we initiated legal proceedings against a third party to enforce a patent covering our product candidates or other technologies, the defendant could counterclaim that the asserted patent is invalid or unenforceable. In patent litigation in the U. S. and in other jurisdictions, defendant counterclaims alleging invalidity or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non- enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise claims challenging the validity or enforceability of our patents before administrative bodies in the U. S. 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, or amendment to our patents in such a way that they no longer cover our product candidates or other technologies. 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 or our licensing partners 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 on our product candidates or other technologies. Such a loss of patent protection would have a material adverse impact on our business, financial condition, results of operations, and growth prospects. Depending upon the timing, duration, and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U. S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch- Waxman Act). The Hatch- Waxman Act permits a patent term extension of up to five years as compensation for patent term lost during 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 extensions as compensation for patent term lost during regulatory review processes are also available in certain foreign countries and territories, such as in Europe under a Supplementary Patent Certificate. However, we may not be granted an extension in the U. S. and / or foreign countries and territories because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain a patent term extension or the term of any such extension is shorter than what we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and growth prospects could be materially harmed. If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed. In addition to seeking patents for our product candidates and other technologies, we also rely on trade secrets and confidentiality agreements to protect our unpatented know- how, technology, and other proprietary information and to maintain our competitive position. We consider trade secrets and know- how to be one of our primary sources of intellectual property. Trade secrets and know- how can be difficult to protect. We expect our trade secrets and know- how to over time be disseminated within the industry through independent development, the publication of journal articles describing the methodology, and the movement of personnel from academic to industry scientific positions. 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, corporate collaborators, outside scientific collaborators, CROs, CDMOs, consultants, advisors, and other third parties. We also enter into confidentiality and invention or patent assignment agreements with our employees and consultants as well as train our employees not to bring or use proprietary information or technology from former employers to us or in their work, and remind former employees when they leave their employment of their confidentiality obligations. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. Despite our efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to obtain adequate remedies for such breaches. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the U. S. 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. If any of our trade secrets were to be disclosed to or independently developed by a competitor or other third party, our competitive position would be materially and adversely harmed. If any of our patent applications do not issue as patents in any jurisdiction, we may not be able to compete effectively. Changes in either the patent laws or their interpretation in the U. S. and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our patents with respect to our product candidates. With respect to our intellectual property related to our product candidates, we cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors or other third parties. The patent prosecution process is expensive, time- consuming, and complex, and we may not be able to file, prosecute, maintain, or enforce all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into nondisclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, outside scientific collaborators, CROs, CDMOs, 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. 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. Furthermore, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the U. S. 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 were the first to make the inventions claimed in any of our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. If the scope of any patent protection we obtain is not sufficiently broad, or if we lose any of our patent protection, our ability to prevent our competitors from commercializing similar or identical technology and product candidates would be adversely affected. The patent position of biotechnology and pharmaceutical 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 pending and future patent applications may not result in patents being issued which protect our product candidates or other technologies or which effectively prevent others from commercializing competitive technologies and product candidates. Moreover, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we own currently or in the future 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 to which we have rights may be challenged, narrowed, circumvented, or invalidated by third parties. Consequently, we do not know whether product candidates or other technologies will be protectable or remain protected by valid and enforceable patents. Our competitors or other third parties may be able to circumvent our patents 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 growth prospects. The issuance of a patent is not conclusive as to its inventorship, scope, validity, or enforceability, and our patents may be challenged in the courts or patent offices in the U. S. and abroad. We may be subject to a third- party pre- issuance submission of prior art to the United States Patent and Trademark Office (USPTO) or become involved in opposition, derivation, revocation, reexamination, post- grant and inter partes review, or interference proceedings or other similar proceedings challenging our patent rights. An adverse determination in any such submission, proceeding, or litigation could reduce the scope of, or invalidate or render unenforceable, such patent rights, allow third parties to commercialize our product candidates or other technologies and compete directly with us, without payment to us, or result in our inability to manufacture or commercialize products without infringing third- party patent rights. Moreover, we may have to participate in interference proceedings declared by the USPTO to determine priority of invention or in post- grant challenge proceedings, such as oppositions in a foreign patent office, that challenge our priority of invention or other features of patentability with respect to our patents and patent applications. Such challenges may result in loss of patent rights, loss of exclusivity, or in patent claims being narrowed, invalidated, or held unenforceable, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our product candidates and other technologies. Such proceedings also may result in substantial cost and require significant time from our scientists and management, even if the eventual outcome is favorable to us. If we are unsuccessful in any such proceeding or other priority or inventorship dispute, we may be required to obtain and maintain licenses from third parties, including parties involved in any such interference proceedings or other priority or inventorship disputes. Such licenses may not be available on commercially reasonable terms or at all or may be non- exclusive. If we are unable to obtain and maintain such licenses, we may need to cease the development, manufacture, and commercialization of one or more of the product candidates we may develop. The loss of exclusivity or the narrowing of our owned and licensed patent claims could limit our ability to stop others from using or commercializing similar or identical technology and products. In addition, given the amount of time required for the development, testing, and regulatory review of new product candidates, patents protecting such product candidates might expire before or shortly after such 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. We may not be able to protect our intellectual property and proprietary rights throughout the world. Filing, prosecuting, and defending patents on our product candidates and other technologies in all countries throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the U. S. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the U. S., or from selling or importing products made using our inventions in and into the U. S. or other jurisdictions.

Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and, further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the U. S. These products may compete with our products, and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trade secrets, and other intellectual property protection, particularly those relating to biotechnology 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. Proceedings to enforce our intellectual property and proprietary rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. 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 or license. 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. 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 U. S. over the lifetime of our owned or licensed patents and applications. 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 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 growth prospects. Changes in U. S. patent law 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 U. S. 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 U. S., the first to invent the claimed invention was entitled to the patent, while outside the U. S., 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 U. S. 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 could therefore be awarded a patent covering an invention of ours even if we 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 U. S. and most other countries are confidential for a period of time after filing or until issuance, we cannot be certain that we were the first to either (i) file any patent application related to our product candidates or other technologies or (ii) invent any of the inventions claimed in our patents or patent applications. The America Invents Act also significantly affects the way patent applications are prosecuted and as well as patent litigation. This includes allowing third party submission of prior art to the USPTO during patent prosecution and additional procedures to attack the validity of a patent by USPTO administered post- grant proceedings, including post- grant review, inter partes review, and derivation proceedings. Because of a lower evidentiary standard in USPTO proceedings as 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 that would not have been invalidated if first challenged by the third party as a defendant in a district court action. Therefore, the America Invents Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. In addition, the patent positions of companies in the development and commercialization of pharmaceuticals are particularly uncertain. Various 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. This combination of events has created uncertainty with respect to the validity and enforceability of patents, once obtained. 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. We may be subject to claims challenging the inventorship of our patents and other intellectual property. We may be subject to claims that former employees, scientific collaborators or other third parties have an interest in our patents, trade secrets, or other intellectual property as an inventor or co- inventor. For example, we may have inventorship disputes arise from conflicting obligations of employees, consultants, or others who are involved in developing our product candidates or other technologies. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership of our patents, trade secrets, or other intellectual property. If the defense of any such claims fails, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property that is important to our product candidates and other technologies. Even if we are successful in defending

against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. We may not be successful in obtaining necessary rights to our product candidates or other technologies. Many pharmaceutical companies, biotechnology companies, and academic institutions that compete with us in the field of neurodegeneration therapy may have patents filed and are likely filing patent applications potentially relevant to our business. In order to avoid infringing these third- party patents, we may find it necessary or prudent to obtain licenses to such patents from such third- party intellectual property holders. We may also require licenses from third parties for certain technologies for use with future product candidates. In addition, with respect to any patents we co- own with third parties, we may wish to obtain licenses to such co- owner' s interest to such patents. However, we may be unable to secure such licenses or otherwise acquire any compositions, methods of use, processes, or other intellectual property rights from third parties that we identify as necessary for our future product candidates. The licensing or acquisition of third- party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third- party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. If we are unable to successfully obtain rights to required third- party intellectual property rights or maintain the existing intellectual property rights we have, we may have to abandon development of the relevant program or product candidate, which could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. **Our expansion into additional indications beyond Alzheimer' s disease may face challenges if we are unable to obtain additional intellectual property rights that may be necessary or desirable. We may leverage our scientific insights in neurodegeneration and neuroinflammation and advanced tools in molecular biology, biochemistry, and imaging to expand our science to other diseases, initially focusing on other central nervous system disorders. New indications and new drug development approaches may complement or supersede our initial focus on Alzheimer' s disease. While we expect certain of our existing intellectual property, such as our patents covering the composition of matter of our drug simufilam, to be important for any such expansion, in order to expand our science to other diseases, for some indications, it may be necessary or desirable that we procure additional intellectual property to support new development programs, including for central nervous system disorders beyond Alzheimer' s disease. In the absence of such additional intellectual property rights, product candidates that we may develop for such additional indications may not be sufficiently covered by intellectual property or such product candidates may be challenged by third parties possessing other intellectual property or exclusive rights in respect thereof. For example, we intend to conduct exploratory preclinical studies in collaboration with the TSCA to better understand simufilam' s potential as a treatment for TSC- related seizures. Based on the results of such additional studies, considered together with academic research conducted at Yale, we will assess whether there is support for an IND application in respect of a proof- of- concept open- label clinical trial for simufilam in TSC- related epilepsy. On February 26, 2025, we entered into the License Agreement with Yale in connection with our development and commercialization of simufilam for the treatment of TSC- related epilepsy. If we fail to comply with our obligations under the License Agreement, Yale may have the right to terminate the License Agreement, in which event we may not be able to advance our development and commercialization plans for simufilam for the treatment of TSC- related epilepsy. In addition, disagreements with Yale, including over the scope of the License Agreement, contract interpretation, or the implementation of our development plan, may cause delays or termination of development or commercialization of simufilam for the treatment of TSC- related epilepsy, or may result in time- consuming and expensive legal proceedings. If we are unable to identify and procure intellectual property necessary or desirable for programs in other indications that we may decide to pursue in the future, it may be more challenging or, in some cases, impracticable to expand into such other indications. There can be no assurance that we will be able to obtain such intellectual property on commercially reasonable terms, or at all, which could have a material adverse effect on our business.** 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 which may prevent or delay the development of our product candidates. The field of developing innovations for neurodegenerative diseases is highly competitive and dynamic. Due to the focused research and development that is taking place by several companies, including us and our competitors, the intellectual property landscape in this field is in flux, and it may remain uncertain in the future. Additionally, no products utilizing our underlying science and technology have yet reached the market. As such, there may be significant intellectual property related litigation and proceedings relating to our, and other third party, intellectual property and proprietary rights in the future. Many of our employees, consultants, and advisors are currently or were previously employed at universities or other biotechnology or pharmaceutical companies, including our competitors and 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 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 growth prospects. Our commercial success depends in part on our ability to develop, manufacture, market, and sell any product candidates that we develop and to use our proprietary technologies without 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. We may become party to, or threatened with, such actions in the future, regardless of their merit. As discussed above, recently, due to changes in U. S. law referred to as patent reform, new procedures including inter partes review and post- grant review have been implemented. As stated above, this reform adds uncertainty to the possibility of challenge to our patents in the future. Numerous U. S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which we are developing our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates and other technologies may give rise to claims of infringement of the patent rights of others. Although we believe that we do not infringe on any third parties' patents or other intellectual property, we cannot assure you that our product candidates and other technologies that we have developed, are developing or may develop in the future will not infringe existing or future patents owned by third parties. We may not be aware of patents that have already been issued to a third party, such as a competitor in the fields in which we are developing product candidates, who might assert infringement of patents it may hold by our current or future product candidates or other technologies, including claims to compositions, formulations, methods of manufacture or methods of use or treatment that cover our product candidates or other technologies. It is also possible that patents owned by third parties of which we are aware, but which we do not believe are relevant to our product candidates or other technologies, could be found to be infringed by our product candidates or other technologies. 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 our product candidates or other technologies may infringe. Engaging in litigation to defend against third parties alleging that we have infringed, misappropriated, or otherwise violated their patents or other intellectual property rights is very expensive, particularly for a company of our size, and time- consuming. 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. Patent litigation and other proceedings may also absorb significant management time. Uncertainties resulting from the initiation and continuation of patent litigation or other proceedings against us could impair our ability to compete in the marketplace. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. 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. Competitors may infringe on our patents or the patents of our licensing partners, or we may be required to defend against claims of infringement. In addition, our patents or the patents of our licensing partners also may become involved in inventorship, priority, or validity disputes. To counter or defend against such claims can be expensive and time consuming. In an infringement proceeding, a court may decide that a patent in which we have an interest is invalid or unenforceable, the other party' s use of our patented technology falls under the safe harbor to patent infringement, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. 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. 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 our product candidates or utilize similar technology but that are not covered by the claims of the patents that we may own; ● we might not have been the first to make the inventions covered by the issued patent or pending patent application that we own now or in the future; ● we might not have been the first to file patent applications covering certain of our inventions; ● others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned intellectual property rights; ● it is possible that our current or future pending patent applications will not lead to issued patents; ● issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors or other third parties; ● our competitors or other third parties might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; ● we may not develop

additional proprietary technologies that are patentable; ● the patents of others may harm our business; and ● we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could have a material adverse effect on our business, financial condition, results of operations, and growth prospects. ~~Our reputation~~ **The Company' s Phase 2b Study was designed as a 28- day, approximately 60- patient, randomized, double- blind, placebo- controlled, multiple dose study. A primary objective of the Phase 2b Study was to measure changes in levels of cerebral spinal fluid (CSF) biomarkers in study participants from baseline value to Day 28. CSF biomarker assays** and ~~operations could be adversely impacted~~ **related bioanalysis for the Phase 2b Study (the CUNY Bioanalysis) were conducted** by ~~allegations of wrongdoing, regardless of their -- the merits~~ **laboratory at CUNY of Dr** . ~~We believe~~ **Hoau- Yan Wang, formerly a paid scientific collaborator, consultant and advisor to Cassava. Based on the CUNY Bioanalysis, Cassava reported statistically significant improvements in CSF biomarkers in treatment groups as compared to the placebo group for the Phase 2b Study. On June 28, 2024, the DOJ announced** that **a federal grand jury in the U. S. District** ~~our~~ **Court for** ~~reputation has significantly contributed to~~ the ~~success~~ **District** of ~~our business~~ **Maryland returned an indictment of Dr** . **Wang alleging** ~~We also believe~~ that ~~maintaining~~ **he caused Cassava to submit grant applications to NIH that contained false** and ~~enhancing our reputation~~ **fraudulent representations about** ~~is~~ **his research. Among other things** ~~critical to many of our core operations~~ , ~~such~~ **the indictment alleges that Dr. Wang made materially false, fraudulent, and misleading statements to NIH regarding the mechanism by which simufilam** ~~as~~ **was** ~~conducting studies, working~~ **designed to treat Alzheimer' s disease and the improvement of certain Alzheimer' s disease indicators in patients treated** with **simufilam** ~~outside vendors~~ , ~~attracting qualified employees, members of~~ **and that Dr. Wang manipulated** ~~our~~ **or otherwise fabricated research results, including Western Blot images that he prepared. The Company' s** Board ~~of~~ **empowered an Ad Hoc Investigation Committee (the Committee), comprising independent** ~~Directors~~ **directors , to direct** ~~and~~ **an investigation (the Internal Investigation) of supplemental information provided** ~~science collaborators, raising funds for future operations, and working with potential industry and government collaborators. Maintaining and enhancing our reputation will depend largely on our ability to develop innovative drug products, continue to generate credible scientific data and respond appropriately to our critics, which we may not do successfully. Our reputation may be injured~~ by the ~~dissemination~~ **SEC. As part** of **an Internal Investigation conducted** ~~false statements purporting to be fact, mischaracterizations of our scientific data, or~~ by ~~hostile actions made by or paid for by parties associated with market participants who seek a decline in~~ the ~~price~~ **Committee, the Committee evaluated information contained in the DOJ indictment** of **Dr. Wang** ~~our securities (" short- sellers ")~~ as well as ~~media~~ **information from the Company' s discussions with the SEC. The Internal Investigation determined that certain statistical information contained in an attachment to an email sent by a former senior employee of Cassava to Dr. Wang before the CUNY Bioanalysis of CSF biomarkers was conducted could have been used to unblind him as to some number of Phase 2b Study participants. Unblinded information, if accessed in connection with bioanalysis, could be improperly utilized to manipulate underlying samples or data to skew reported results. The Internal Investigation did not determine, and may never be able to determine with any reasonable degree of certainty, whether Dr. Wang unblinded himself as to some number of Phase 2b Study participants. Nevertheless, the fact that Dr. Wang possessed information that could have been used to so unblind himself, together with the allegations in the DOJ indictment, undermine the blinded study design and create substantial uncertainty about the validity of the CUNY Bioanalysis of CSF biomarkers. In addition, another objective of the Phase 2b Study was to measure changes in cognitive outcome measures using the Cambridge Neuropsychological Test Automated Battery, or CANTAB, over the 28- day study period. In connection with our settlement with the SEC, the SEC' s complaint alleged, among other things, that disclosures relating to the Phase 2b Study' s cognition results (the Cognition Disclosures), which reported results from a post hoc sensitivity analysis, were inadequate and misleading. Accordingly, in light of the foregoing uncertainties and allegations, you should not rely on the CUNY Bioanalysis of CSF biomarkers reported by the Company in connection with the Phase 2b Study or the Cognition Disclosures from the Phase 2b Study. There can be no assurance that such uncertainties and allegations will not adversely impact any FDA review with respect to simufilam following completion of our Phase 3 clinical studies or cause the FDA to request additional information regarding simufilam. We are defending ourselves in a number of lawsuits, including securities class action and shareholder derivative actions, and the Company, as well as two former senior employees of the Company, have been and may continue to be subject to governmental investigations and inquiries. Defending litigation and responding to governmental investigations is expensive and time consuming and may divert the time and attention of our management away from the conduct of our primary business. Moreover, the allegations underlying such litigation and governmental investigations have damaged our business reputation, which may make it difficult to, among other things: raise capital or engage in a strategic transaction on acceptable terms or at all; hire and retain third- party consultants and collaborators; recruit and retain patients for our studies; and attract and retain qualified executive officers, other employees and directors. As a result of current or future lawsuits, we may have to pay significant damages or amounts in settlement above insurance** coverage ~~of the foregoing. Allegations~~ , **including amounts** ~~mischaracterizations and similar statements may be disseminated directly to third parties with whom we interact, published~~ in ~~forums over which we have no control, such as through online social media channels~~ **respect of indemnification obligations of the Company to former officers and senior employees. An unfavorable outcome or prolonged litigation could materially and adversely impact** ~~or~~ **our** ~~publicized as a~~ **business, operating** ~~result~~ **results** ~~of media coverage~~ , and **financial condition, including** ~~may be adopted by the editors of scientific or~~ **our** ~~technical journals that have published~~ **cash runway. In addition, current** ~~our~~ **or** ~~research~~ **future government investigations and inquiries could subject us to various sanctions** , ~~potentially resulting in retractions~~ **including significant penalties,** ~~or~~ **our** ~~expressions of concern by~~ **being prevented from receiving government grants, and** ~~the~~ **other** ~~journals~~ **punitive measures** . For example,

~~although no journal~~ **the Company paid a civil monetary penalty of $ 40 million in November 2024** ~~has~~ **as part** ~~asserted that we or any~~ of **a settlement with the SEC resolving the SEC investigation of the Company' s disclosures regarding its Phase 2b Study and related matters. Such payments** ~~our~~ **or** ~~employees~~ **settlement arrangements in current or future litigation and government investigations and inquiries could significantly and adversely impact** ~~or~~ **our reputation and divert management' s attention and resources** ~~consultants has inappropriately manipulated data or engaged in any misconduct~~, **which could** ~~public short- seller allegations~~ have **a material adverse effect on** ~~prompted several journals to reassess certain peer- reviewed articles previously published by researchers associated with us and to retract articles or~~ **our business** ~~issue expressions of concern. Regardless of merit~~, **operating results** ~~allegations, mischaracterizations~~ and **financial condition** ~~false statements may spread quickly and erode confidence in our reputation~~. **While we cannot estimate** ~~Maintaining and enhancing our reputation may require us to make substantial investments in legal actions or~~ **our** ~~other activities~~ **potential exposure to future litigation**, **regulatory claims** ~~and these investments could be expensive~~, **investigations or proceedings at this** time ~~consuming~~, ~~and unsuccessful. If~~ we ~~fail~~ **have already incurred significant expense related** to **litigation** ~~successfully maintain our reputation~~, ~~or if we~~ **government investigations and the Internal Investigation and expect to continue to** incur ~~excessive~~ **significant** ~~expenses~~ **expense** ~~in this effort, our business, operations, future prospects, cash flows, and financial position may be adversely affected~~. Our current dependence on single source suppliers for our drug substance and drug product could materially adversely affect our ability to manufacture our product candidates and materially increase our costs. We rely on single source suppliers for materials that are critical to the manufacturing of simufilam, our lead product candidate. This reliance subjects us to risks related to our potential inability to obtain an adequate supply of required materials. If these third parties do not successfully carry out their contractual duties, meet expected deadlines or conduct their activities in accordance with regulatory requirements, or if there are disagreements between us and these third parties, we may not be able to complete, or may be delayed in completing, the clinical studies required to support future regulatory submissions and approval of the product candidates we develop. Our operating results could be materially adversely affected if we were unable to obtain adequate supplies of simufilam in a timely manner or if their cost increased significantly due to inflation or other factors. Further, under certain circumstances, service providers that have contracted with us may be entitled to terminate their engagements with us. In such circumstances, product development activities could be delayed while we seek to identify, validate, and negotiate an agreement with a replacement service provider. In some such cases an appropriate replacement may not be readily available or available on acceptable terms, which could cause additional delays to our development process. It would likely result in production and delivery delays if we needed to find alternative suppliers for simufilam, which could lead to delays in our clinical trials and have a material adverse effect on our business, results of operations and financial condition Inadequate Congressional funding for the FDA, the SEC and other U. S. government agencies or comparable foreign regulatory authorities, including from government shut downs, or other disruptions to these agencies' operations, could hinder these agencies' ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent government agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA or comparable foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and enact statutory, regulatory and policy changes. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid, unpredictable and entirely beyond our control. Disruptions at the FDA and other agencies may also slow the time necessary for us and the FDA to communicate and ~~continue discussions~~ ---- **discuss** ~~on~~ key aspects of our ~~Phase 3~~ clinical ~~analysis~~ **program**, or for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, in prior years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA or SEC to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. The FDA may change the statutory requirements for drug approval. FDA Guidances for Industry are non- binding policy documents that are issued by FDA from time to time to assist sponsors, such as our Company, with the clinical development of drug candidates. Even though such guidance documents do not set legal standards or impose binding requirements they are nonetheless broadly followed by sponsors, including us. In addition, sponsors who adhere in good faith with earlier guidance documents have no assurance or recourse against enforcement actions if the guidance documents are later replaced with conflicting guidance. We have relied heavily on current FDA guidance and meetings with the FDA to advance simufilam through the drug development process. Any future changes to existing FDA Guidance for Industry for ~~Alzheimer' s disease~~ **indications that we are pursuing** may have a material adverse effect on our business, may add significant time, cost or complexity to our drug development program for simufilam, or could cause us to cease or delay development of some or all our product candidates. In addition, changes in FDA regulations, statutes or the interpretation of existing regulations and statutes could impact our business by requiring, for example: (i) changes to our manufacturing arrangements for simufilam; (ii) additions or modifications to product labeling, if and when our product candidates are approved for sale; (iii) the recall or discontinuation of our product candidates from investigational clinical sites; or (iv) additional record- keeping requirements. If any such changes were to be imposed, they may have a material adverse effect on our business, may add significant time, cost or complexity to our drug development program for simufilam, or could cause us to cease or delay development of some or all our product candidates. We do not have any

manufacturing facilities. We currently **expect to** rely on CDMOs for all of the manufacture of our materials for preclinical studies and clinical ~~studies and expect to continue to do so for preclinical~~ studies, clinical studies, and for commercial supply of any product candidates that we may develop. We currently have established relationships with several CDMOs for the manufacturing of our product candidates. We may be unable to establish any further agreements with CDMOs or to do so on acceptable terms. Even if we are able to establish agreements with third- party manufacturers, reliance on CDMOs entails additional risks, including: ● the possible breach of the manufacturing agreement by the third party; ● the possible termination or nonrenewal of the agreement by the third party at a time that is costly or inconvenient for us; ● reliance on the third party for regulatory compliance, quality assurance, safety, and pharmacovigilance and related reporting; and ● the inability to produce required volume in a timely manner and to quality standards. Third- party manufacturers may not be able to comply with cGMP regulations or similar regulatory requirements outside the U. S. Our failure, or the failure of our CDMOs, to comply with applicable regulations could result in clinical holds on our studies, sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures, or recalls of product candidates or product candidates, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business, financial condition, results of operations, and growth prospects. Any product candidates that we may develop may compete with other product candidates and products for access to manufacturing facilities. There are a limited number of manufacturers that operate under cGMP regulations and that might be capable of manufacturing for us. Any performance failure on the part of our existing or future third- party manufacturers could delay clinical development or marketing approval. If any one of our current contract manufacturers cannot perform as agreed, we may be required to replace that manufacturer and may incur added costs and delays in identifying and qualifying any such replacement. Furthermore, securing and reserving production capacity with contract manufacturers may result in significant costs. We also rely on third-parties for the supply of the raw materials required for the production of our product candidates, and we expect to continue to rely on third party manufacturers for the commercial supply of any of our product candidates for which we obtain marketing approval. Our current and anticipated future dependence upon others for the manufacture of any product candidates we may develop may adversely affect our future profit margins and our ability to commercialize any medicines that receive marketing approval on a timely and competitive basis. Our employees, principal investigators, consultants and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants and vendors. Misconduct by these parties could include intentional failures, reckless and / or negligent conduct or unauthorized activities that violate (i) the laws and regulations of FDA and other regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (ii) manufacturing standards, (iii) federal and state data privacy, security, fraud and abuse and other healthcare laws and regulations in the United States and abroad and (iv) laws that require the true, complete and accurate reporting of financial information or data. In particular, clinical and business arrangements in the biotechnology and healthcare industries are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing and other abusive practices. These laws and regulations restrict or prohibit a wide range of financial arrangements, incentive programs and other business arrangements. Such misconduct also could involve the improper use of individually identifiable information, including, without limitation, information obtained in the conduct of clinical trials, creating fraudulent data in our 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 government investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. Additionally, 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 result in significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participating in government-funded healthcare programs, such as Medicare and Medicaid, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with these laws, contractual damages, reputational harm and the curtailment or restructuring of our operations, any of which could have a negative impact on our business, financial condition, results of operations and prospects. **On January 7, 2025, we announced a reduction in our workforce by 10 employees, a reduction of 33 %. The Workforce Reduction was intended to align our human capital resources to meet our strategic goals, in light of the discontinuation of our ongoing clinical trials for Alzheimer' s disease. Headcount reductions, which may result in the loss of institutional knowledge and expertise, may adversely affect operations and yield unintended consequences, such as attrition beyond our intended reductions and reduced employee morale. Our ability to successfully execute on our strategy depends on retaining key remaining personnel, and unanticipated attrition, which may occur on short notice, could potentially harm our business and operations. As a result of the Workforce Reduction, our management may need to divert attention away from day- to-day strategic and operational activities and devote additional time to managing organizational changes.** Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud. We are subject to the periodic reporting requirements of the Exchange Act. We designed our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or furnish under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well- conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. These inherent limitations include the realities that judgments in decision- making can be faulty, and that breakdowns can occur because of simple mistake

or human error. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected. Failure to comply with laws regarding data privacy could expose us to risk of enforcement actions and penalties under such laws. We may be subject to privacy and security laws in the various jurisdictions in which we operate, obtain or store personally identifiable information. The legislative and regulatory landscape for privacy and data protection continues to evolve, and there has been an increasing focus on privacy and data protection issues with the potential to affect our business. Our ongoing efforts to comply with evolving laws and regulations may be costly and require ongoing modifications to our policies, procedures and systems. Failure to comply with laws regarding data protection by us or our partners or service providers would expose us to risk of enforcement actions and penalties under such laws. Even if we are not determined to have violated these laws, government investigations into these issues typically require the expenditure of significant resources and generate negative publicity, which could harm our business, financial condition, results of operations or prospects. Within the U. S., there are numerous federal and state laws and regulations related to the privacy and security of personal information. For example, at the federal level, the Health Insurance Portability and Accountability Act of 1996, as amended (" HIPAA "), and its implementing regulations establish privacy and security standards that limit the use and disclosure of personally identifiable health information, or protected health information, and require the implementation of administrative, physical and technological safeguards to protect the privacy of protected health information. While we have determined that we are neither a " covered entity " nor a " business associate " directly subject to HIPAA, many of the U. S. health care providers with which we interact are subject to HIPAA, and we may have assumed obligations related to protecting the privacy of personal information. States are increasingly regulating the privacy and security of personal information. For example, the California Consumer Privacy Act ("CCPA "), which took effect in 2020, gives California consumers (defined to include all California residents) certain rights, including the right to ask covered companies to disclose the types of personal information collected, the categories of sources from which such information was collected, the business purpose for collecting or selling the consumer' s personal information, the categories of third parties with whom a covered company shares personal information, and specific pieces of information collected by a covered company. The CCPA imposes several obligations on covered companies to provide notice to California consumers regarding their data processing activities. The CCPA also gives California consumers the right to ask covered companies to delete a consumer' s personal information and it places limitations on a covered company' s ability to sell personal information, including providing consumers a right to opt out of sales of their personal information. Additionally, the California Privacy Rights Act ("CPRA "), which became operational in 2023, significantly modifies the CCPA, including expanding consumers' rights with respect to certain sensitive personal information, and creates a new state agency vested with authority to implement and enforce the CCPA and CPRA. The Virginia Consumer Data Protection Act ("CDPA ") went into effect on January 1, 2023. The CDPA provides consumers with new rights to access, correct, delete and obtain a copy of the personal information a covered business holds about them, and to opt out of certain data processing activities ~~. Because we are developing our lead product candidate for the treatment of Alzheimer' s disease, a condition for which there are few recent examples of new drug molecules that have received full FDA approval, and all Phase 3 trials in Alzheimer' s disease employ cognitive and functional efficacy endpoints or methodologies that may be considered subjective, there is a heightened risk that the FDA or other regulatory authorities may not consider our Phase 3 clinical trials, or the endpoints of our clinical trials, as evidence of clinically meaningful results or that our clinical results may be difficult to analyze. If our product candidates advance to the FDA review process, we will need to demonstrate the achievement of success criteria and endpoints such that the FDA will be able to determine the clinical efficacy and safety profile of our product candidates. Because we are developing a novel treatment for Alzheimer' s disease, a condition in which there are very few examples of new drug approvals, and our trials employ endpoints or methodologies that may be considered subjective, there is heightened risk that the FDA or other regulatory bodies may not consider our clinical trials, or the endpoints of our clinical trials, as evidence of clinically meaningful results to patients. In addition, the resulting clinical data and results may be difficult to analyze. Even if the FDA does find our success criteria to be sufficiently validated and clinically meaningful, we may not achieve the pre- specified endpoints to a threshold of statistical significance (i. e., p- value < 0. 05). Even if we believe the data collected from clinical trials of our lead product candidates are promising, these data may not be sufficient to support approval by the FDA or foreign regulatory authorities. Pre- clinical and clinical data can be interpreted in different ways. Accordingly, the FDA or foreign regulatory authorities could interpret these data in different ways from us, which could delay, limit or prevent regulatory approval. If data from one or both of our Phase 3 trials do not adequately demonstrate the safety or efficacy of our lead product candidate, the regulatory approval for such product candidate could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approvals could be denied. We are evaluating two doses (50 mg and 100 mg) of simufilam in on- going Phase 3 trials. If data from one dose in our Phase 3 trials does not adequately demonstrate safety or efficacy, the regulatory approval for the other dose could be significantly delayed as we work to meet approval requirements, or, if we are not able to meet these requirements, such approval could be denied. As our development plans and strategies develop, we expect to add a significant number of additional managerial, operational, financial, and other personnel. Future growth will impose significant added responsibilities on members of management, including: ● identifying, recruiting, integrating, retaining, and motivating additional employees; ● increasing employee headcount; ● managing our internal development efforts effectively, including the clinical and FDA review process for our current and future product candidates, while complying with our contractual obligations to contractors and other third parties; ● expanding our operational, financial and management controls, reporting systems, and procedures; and ● managing increasing operational and managerial complexity. Our future financial performance and our ability to continue to develop and, if approved, commercialize our product candidates will depend, in part, on our ability to effectively manage any future growth. Our management may also have to divert a disproportionate amount of its attention away from day- to- day activities in order to~~

~~manage these growth activities. We currently rely, and for the foreseeable future will continue to rely, in substantial part on certain independent organizations, advisors, and consultants to provide certain services. There can be no assurance that the services of these independent organizations, advisors, and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements. In addition, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical studies may be extended, delayed, or terminated, and we may not be able to obtain regulatory approval of our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, if at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop our product candidates and, accordingly, may not achieve our research, development, and commercialization goals~~ . Ownership of our corporate headquarters and property leasing are subject to numerous risks and uncertainties. In 2021, we made an all- cash purchase of an office complex in Austin, Texas, a portion of which serves as our corporate headquarters. Title to this property is held by Austin Innovation Park, LLC, a Texas limited liability company wholly owned by Cassava Sciences. The purchase required a substantial upfront cash investment and may require further commitments of our resources in the future. We have assumed or entered into lessor commitments with independent third parties for portions of our office complex and expect to continue to do so in the future. Commercial property ownership and related leasing activity are subject to many factors that pose substantial financial risks and uncertainties, including tenant default or non- payment of lease obligations by tenants. Macro- economic or other factors outside of our control could have an adverse effect on the demand for leased office space in our locale or may cause a decline in the market value of our corporate headquarters. At December 31, ~~2023~~ **2024** , we occupied approximately 25 % of the property with the remainder either leased or available for lease to third parties. **Most** ~~Virtually all existing~~ tenant leases ~~will expire~~ **expired** in 2024. We ~~believe tenant leases that expire~~ **expect to record a net loss on leasing activities** in ~~2024~~ **2025 as the higher vacancy rates** ~~will likely not be extended, renewed or re~~ **are expected to significantly lower** ~~- leased beyond their expiry date, in which case we will no longer receive~~ rental **income** ~~payments or reimbursement for shared expense for such office space~~ . If we fail to lease unoccupied office space at favorable rates, or if we incur excessive expenses in this effort or incur excessive leasehold improvements or property ownership expenses, our business, operations, future prospects, cash flows, and financial position may be adversely affected. In addition, our property is located in a semi- rural, wooded area of Austin, Texas that is subject to natural disasters such as extreme weather conditions, including but not limited to floods, tornadoes, wildfires, winter storms, lighting, heat waves and drought. Such natural disasters could damage, destroy or impair the value of our property or reduce the number of tenants who are willing or able to continue to lease office space in our property. We may incur substantial expenses as a result of our property' s exposure to natural disasters, which could have a material adverse effect on our business and prospects. In the ordinary course of our business, we collect and store sensitive data, including legally protected patient health information, personally identifiable information about our employees, intellectual property, and proprietary business information. We manage and maintain our applications and data utilizing on- site systems, as well as extensive cloud- based applications and data storage. These applications and data encompass a wide variety of business- critical information including research and development information, commercial information and business and financial information. Despite the implementation of security measures, our internal computer systems and those of our current or future CROs and other contractors and consultants may be vulnerable to damage from computer viruses and unauthorized access. As the cyber- threat landscape evolves, these cyberattacks are growing in frequency, sophistication, and intensity, and are becoming increasingly difficult to detect. Such attacks could include the use of key loggers or other harmful and virulent malware, including ransomware or other denials of service, and can be deployed through malicious websites, the use of social engineering, and / or other means. If a breakdown, cyberattack, or other information security breach were to occur and cause interruptions in our operations, it could result in a misappropriation of confidential information, including our intellectual property or financial information, and a material disruption of our development programs and our business operations. For example, the loss of clinical study data from completed, ongoing, or future clinical studies could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Likewise, we rely on our third- party research institution collaborators for research and development of our product candidates and other third parties for the manufacture of our product candidates, to conduct clinical studies, and to analyze our clinical study data and similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or systems, or inappropriate disclosure of confidential, financial, or proprietary information, including data related to our personnel, we could incur liability or risk disclosure of confidential, financial, or proprietary information, and the further development and commercialization of our product candidates could be delayed. There can be no assurance that we and our business counterparties will be successful in efforts to detect, prevent, or fully recover systems or data from all breakdowns, service interruptions, attacks, or breaches of systems that could adversely affect our business and operations and / or result in the loss of critical or sensitive data, which could result in financial, legal, business, or reputational harm to us **. We are in the early stages of exploring potential AI capabilities and related data analytics. As an emerging and rapidly evolving technology, our use of AI presents risks that could adversely affect our operations, information security and reputation. AI systems may produce inaccurate or flawed outputs due to flawed algorithms, or insufficient and / or erroneous training data. Reliance on flawed outputs could result in lower quality decision- making or prevent us from effectively utilizing AI in our business. We may also become vulnerable to operational disruptions if the AI technologies we use experience downtimes or are compromised by cyberattacks. If we do not effectively implement guardrails and train our staff on the safe and proper use of AI, or if our staff fail to effectively adhere to our established guardrails and training on the use of AI, we may experience adverse effects on our business, including data**

breaches, the loss of confidential information (including our intellectual property), unintentional disclosure of personal data, or other misuse of our proprietary information, any of which could result in significant reputational harm and could have a material adverse effect on our business and results of operations . Our reliance on third parties requires us to share our proprietary information, which increases the possibility that a competitor will discover this information or that our proprietary information will be misappropriated or inadvertently disclosed. Our reliance on third- party vendors requires us to disclose our proprietary information to these parties, which could increase the risk that a competitor will discover this information or that our proprietary information will be misappropriated or disclosed without our intent to do so. If any of these events were to occur, then our ability to obtain patent protection or other intellectual property rights could be irrevocably jeopardized, and costly, distracting litigation could ensue. Furthermore, if these third- party vendors cease to continue operations and we are not able to quickly find a replacement provider or we lose information or items associated with our products or product candidates, our development programs may be delayed. Although we carefully manage our relationships with our third- party collaborators and CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, clinical operations, financial condition and prospects. Our business involves environmental risks that may result in liability for us. In connection with our research and development activities, we, and our collaborators and vendors, are subject to federal, state and local laws, rules, regulations and policies governing the use, generation, manufacture, storage, air emission, effluent discharge, handling and disposal of certain materials, biological specimens, chemicals and wastes. Although we believe that we comply with such applicable laws, regulations and policies in all material respects and have not been required to correct any material noncompliance, we may incur significant costs to comply with environmental and health and safety regulations in the future. Although we believe that our safety procedures for handling and disposing of controlled materials comply with the standards prescribed by state and federal regulations, accidental contamination or injury from these materials may occur. In the event of such an occurrence, we could be held liable for any damages that result and any such liability could exceed our resources. Our operations, and those of our third- party research institution collaborators, CROs, CDMOs, suppliers, and other contractors and consultants, could be subject to earthquakes, power shortages, telecommunications failures, water shortages, floods, hurricanes, typhoons, fires, extreme weather conditions, disease epidemics or pandemics, ~~such as COVID- 19,~~ and other natural or man-made disasters or business interruptions, for which we are partly or entirely uninsured. In addition, we rely on third parties for conducting certain research and development activities relating to our product candidates, and they may be affected by government shutdowns or withdrawn funding. The occurrence of any such business disruptions could seriously harm our operations and financial condition and increase our costs and expenses. We rely on third party manufacturers to produce and process our product candidates. Our ability to obtain clinical supplies of our product candidates could be disrupted if the operations of these suppliers are affected by a man- made or natural disaster or other business interruption. Our day- to- day operations are located in a single office facility in Austin, Texas. Damage or extended periods of interruption to our corporate, development, or research facilities could cause us to cease or delay development of some or all our product candidates. Our insurance might not cover losses under such circumstances and our business may be seriously harmed by such delays and interruption. As social media continues to expand, it also presents us with new challenges. The inappropriate or unauthorized use of our confidential information on media platforms could cause brand damage or information leakage, which would cause legal or regulatory issues for us. In addition, negative, inappropriate or inaccurate posts or comments about us or our product candidates on social media internet sites could quickly and irreversibly damage our reputation, image and goodwill. Further, the accidental or intentional disclosure of non- public sensitive information by our workforce or others through media channels could lead to information loss or could lead to legal or regulatory issues for us. In addition, there is a risk of a fraudulent third-party hijacking our information technology systems without our knowledge to access our confidential documents or to use our company name, logo or brand without authorization. If any of these events were to occur or we otherwise fail to comply with applicable regulations, we could incur liability, face restrictive regulatory actions or incur other harm and costs to our business. We are a small company with a limited number of employees. We are highly dependent on our key personnel, and if we are not successful in attracting, motivating, and retaining highly qualified personnel, we may not be able to successfully implement our business strategy. Our ability to compete in the highly competitive biotechnology and pharmaceutical industries depends upon our ability to attract, motivate, and retain highly qualified managerial, scientific, and medical personnel. We are highly dependent on our management ~~, particularly our President and Chief Executive Officer, Remi Barbier,~~ and our scientific and technical personnel. The loss of the services provided by any of our executive officers, other key employees, and other scientific and medical advisors, and our inability to find suitable replacements, could result in delays in the development of our product candidates and harm our business ~~. Competition for skilled personnel is intense and the turnover rate can be high, which may limit our ability to hire and retain highly qualified personnel on acceptable terms or at all. We expect that we may need to recruit talent from outside of our region in Austin, Texas, and doing so may be costly and difficult~~ . To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have provided equity option grants that vest over time and / or a cash bonus plan. The value to employees of these equity grants that vest over time or cash bonus plans may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Although we have employment agreements with our key employees, these employment agreements provide for at- will employment, which means that any of our employees could leave our employment at any time, with or without notice. If we are unable to attract and incentivize quality personnel on acceptable terms, or at all, it may cause our business and operating results to suffer. We may need to cease our operations if we are unable to attract and retain key personnel. We are engaged in developing early- and clinical- stage technologies and will continue to do so for the foreseeable future. Unlike larger organizations, we rely on a very small number of highly skilled, and highly sought after, employees to continue the advancement of our development stage technologies. The knowledge and skills contributed by our key employees

may be irreplaceable and the loss of a key employee may cause substantial negative financial, operational and scientific consequences for our business. As an example, ~~in the past, we have received research grant awards from NIH, which depended in part on the continued participation of certain key employees, known as Principal Investigators. When such NIH grant awards are in place, the loss of a Principal Investigator may result in the loss of one or more of such research grant awards. Likewise,~~ the intellectual property that is intended to protect our development stage technologies is still evolving and its evolution remains highly dependent on a small number of employees with specific expertise. The loss of a key employee may jeopardize our existing or pending intellectual property or may prevent us from accessing the technical information and knowledge necessary to extend our portfolio of intellectual property. Furthermore, we believe the adverse effects that may result from losing a key employee' s participation cannot be compensated with any specific insurance policies, such as " key person " or " business life " insurance. If we are not successful in retaining key employees, our business and financial condition will suffer, and we may need to cease our operations. If our current research collaborators or scientific advisors terminate their relationships with us or develop relationships with a competitor, our ability to continue our business operations could be adversely affected. We have relationships with unaffiliated research collaborators at academic and other institutions who conduct research at our request. These research collaborators are not our employees. As a result, we have limited control over their activities and, except as otherwise required by our collaboration agreements, can expect only limited amounts of their time to be dedicated to our activities. Our ability to discover drugs and biomarkers involved in human disease and validate and commercialize diagnostic tests may depend in part on the continuation of these collaborations. If any of these collaborations are terminated, we may not be able to enter into other acceptable collaborations. In addition, our existing collaborations may not be successful. Our research collaborators and scientific advisors may have relationships with other commercial entities, some of which could compete with us. Our research collaborators and scientific advisors sign agreements which provide for the confidentiality of our proprietary information and the results of studies conducted at our request. We may not, however, be able to maintain the confidentiality of our technology and other confidential information related to all collaborations. The dissemination of our confidential information could have a material adverse effect on our business. Our business may be impacted by political events, war, terrorism, business interruptions and other geopolitical events and uncertainties beyond our control. War, terrorism, geopolitical uncertainties and other business interruptions could cause damage to, disrupt or cancel the conduct of our clinical studies on a global or regional basis, which could have a material adverse effect on our business, clinical sites or vendors with which we do business. Such events could also decrease patient demand to enroll in our clinical studies or make it difficult or impossible for us to deliver products and services to our clinical investigational sites. In addition, territorial invasions can lead to cybersecurity attacks on technology companies, such as ours, located far outside of the conflict zone. In the event of prolonged business interruptions due to geopolitical events, we could incur significant losses, require substantial recovery time and experience significant expenditures in order to resume our business or clinical operations. We have no operations in Israel, Russia or the Ukraine, but we do not and cannot know if the current uncertainties in these geopolitical areas may escalate and result in broad economic and security conditions or rationing of medical supplies, which could limit our ability to conduct clinical trials outside the U. S. or result in material implications for our business. In addition, our insurance policies typically contain a war exclusion of some description and we do not know how our insurers are likely to respond in the event of a loss alleged to have been caused by geopolitical uncertainties. Our efforts to minimize the likelihood and impact of a cybersecurity incident may not be successful and our business could be negatively affected by a data breach or other cybersecurity threat or other disruption to our operations, which could result in legal claims against us or could give rise to substantial financial costs to redress any such cybersecurity incident and could harm our relationship with vendors, clinical study participants or regulators. Our business operation is data- intensive and relies extensively on the use of information technology. In addition, biopharmaceutical firms have been subject to an increasing number of cyberattacks in recent years, particularly cyberattacks targeting the theft of intellectual property and unauthorized access to proprietary clinical research data or sensitive patient information. Given the nature of our business, we are subject to a variety of evolving cybersecurity threats to our information technology infrastructure, including ransomware, unauthorized attempts to gain access to our operations or to sensitive patient information, denial- of- service attacks or various other methods of attacks. As discussed below, similar security threats may be faced by our vendors, consultants, suppliers, subcontractors, clinical investigational sites and non- clinical research labs. Such cybersecurity threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer " hackers, " threat actors, nation states and rogue nation- state actors. We could also be impacted by the improper cyber conduct of our employees or others working on behalf of us who have access to our proprietary information or sensitive patient information, which could adversely affect our business and reputation. The occurrence of any material cybersecurity incident could cause substantial disruptions to our business operations. In addition to cyber threats, we may face threats to the security of our facilities or executives, which could materially disrupt our business if carried out. We also work cooperatively with numerous vendors, consultants, suppliers, subcontractors, clinical investigational sites and non- clinical research labs, which have access to our proprietary or sensitive information. These third parties, which are typically outside our control, may have varying levels of cybersecurity expertise and safeguards and our ability to monitor their cybersecurity practices is limited. These third parties may not have adequate cybersecurity measures in place, and incidents or other interruptions suffered by them could cause us to experience adverse consequences. In particular, cybersecurity incidents in our drug supply chain could have an adverse impact on our ability to timely deliver product candidates to patients and physicians participating in our clinical studies, which could cause us to delay or cancel the completion of our ongoing clinical and non- clinical studies. If cybersecurity threats materialize and we or third- parties that we rely upon are unable to defend against them or to protect sensitive information, including through complying with evolving information security and data protection / privacy regulations, this could cause vendors, clinical study participants, clinical study investigation sites, patients, or governmental authorities to question the adequacy of the threat mitigation and detection processes and procedures that we and our vendors employ. Moreover, depending

on the severity of an incident, our proprietary clinical research data, sensitive patient information, intellectual property, including trade secrets and research, development and technical know- how, could be compromised. Nearly all of our operations carry cybersecurity risks, including risks that they could be breached or that we could fail to detect, prevent or combat attacks, which could result in financial losses and claims against us, and could harm our relationships with our vendors or clinical study participants. The costs and expenses to respond to a material cybersecurity incident or other security threat or disruption may be substantial for a company of our size. Further, **our** ~~we do not carry a separate~~ cybersecurity commercial insurance policy covering ~~the~~ potential financial losses that may occur in the event we experience a cybersecurity incident **may not be sufficient to cover any related damages or losses** . We have incurred net losses in each reporting period since our inception, including a net loss of $ ~~97~~ **24** . ~~2~~ **3** million for the year ended December 31, ~~2023~~ **2024** . As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of $ ~~380~~ **405** . ~~8~~ **1** million. We have invested significant financial resources in research and development activities for product candidates. We do not expect to generate revenue from product sales for several years, if at all. The amount of our future net losses will depend, in part, on the level of our future expenditures and revenue. Moreover, our net losses may fluctuate significantly from quarter to quarter and year to year, such that a period- to- period comparison of our results of operations may not be a good indicator of our future performance. We expect to continue to incur ~~significant~~ **operating** expenses and ~~higher operating~~ losses for the foreseeable future. We anticipate our expenses will remain substantial as we: ● continue our research and discovery activities; ● advance our current and any future product candidates through preclinical and clinical development; ● initiate and conduct additional preclinical, clinical, or other studies for our product candidates; ● work with our CDMO' s ~~to scale up the manufacturing processes~~ for **the manufacture of** our product candidates; ● seek regulatory approvals and marketing authorizations for our product candidates; ● obtain, maintain, protect, defend and enforce our intellectual property portfolio; ● attract, hire, and retain qualified personnel; ● provide additional internal infrastructure to support our continued research and development operations and any planned commercialization efforts in the future; ● experience any delays or encounter other issues related to our operations; ● meet the requirements and demands of being a public company; and ● defend against litigation, claims or other uncertainties that may arise from allegations made against us or our collaborators. Our prior losses and expected future losses have had and will continue to have an adverse effect on our stockholders' equity and working capital. In any quarter, our operating results could be below the expectations of securities analysts or investors, which could cause our stock price to decline. We have broad discretion in the use of our capital resources, including the net proceeds from any of our financing transactions, and we may not use them effectively. We have broad discretion in the application of our capital resources, including the net proceeds from our financing transactions, and investors will not have the opportunity to opine on whether such resources are being used appropriately. We could spend such capital resources in ways that vary substantially from their initially communicated intended use, do not improve our results of operations or enhance the value of our common stock. Our failure to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest available capital resources, including net proceeds from our financing transactions, in a manner that does not produce income or that loses value **.** We have no products approved for commercial sale. To obtain revenues from the sales of our product candidates that are significant or large enough to achieve profitability, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing, and marketing product candidates with significant commercial value. This is a significant endeavor that few early- stage biopharmaceutical companies can successfully achieve. Our ability to generate revenue and achieve profitability depends on many factors, including: ● completing research and preclinical and clinical development of our product candidates; ● obtaining regulatory approvals and marketing authorizations for product candidates for which we successfully complete clinical development; ● developing a sustainable and scalable manufacturing process for our product candidates, as well as establishing and maintaining commercially viable supply relationships with third parties that can provide adequate products and services to support clinical activities and commercial demand for our product candidates; ● identifying, assessing, acquiring, and / or developing new product candidates; ● negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter; ● addressing any competing technological and market developments; ● maintaining, protecting, expanding, and enforcing our portfolio of intellectual property rights, including patents, trade secrets, and know- how; and ● attracting, hiring, and retaining qualified personnel. Because of the numerous risks and uncertainties associated with drug development, we are unable to predict the timing or amount of our expenses, or when we will be able to generate any meaningful revenue or achieve or maintain profitability, if ever. In addition, our expenses could increase beyond our current expectations if we are required by FDA or foreign regulatory agencies to perform studies in addition to those that we currently anticipate, or if there are any delays in any of our clinical studies or the development of any of our product candidates. We may require additional capital to fund our operations and to complete the development of our product candidates. A failure to obtain this necessary capital on acceptable terms, or at all, could force us to delay, limit, reduce, or terminate our commercialization efforts, product development, or other operations. Our operations have required substantial amounts of cash since inception, and we expect our expenses to remain substantial for the foreseeable future. To date, we have financed our operations primarily through the sale of equity securities, research grants and payments received from prior third- party collaborations. Developing our product candidates and conducting clinical studies for the treatment of neurodegenerative diseases, including Alzheimer' s disease, will require substantial amounts of capital. We will also require a significant amount of capital to commercialize any approved products. As of December 31, ~~2023~~ **2024** , we had cash and cash equivalents of $ ~~121~~ **128** . ~~1~~ **6** million ~~. In addition, from January 3, 2024 to February 26, 2024, we received gross proceeds of approximately $ 21. 8 million from the exercise of outstanding warrants. See Note 13 to the consolidated financial statements for more information~~ . Based on our current operating plan, we believe that our existing cash and cash equivalents will be sufficient to fund our projected operations for at least the next 12 months. Our estimate as to how long we expect our existing cash and cash equivalents to be available to fund

our operations is a forward- looking statement, based on assumptions that may prove inaccurate, and we could use our available capital resources sooner than we currently expect. In addition, changing circumstances may cause us to increase our spending significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of currently unanticipated circumstances, which may be beyond our control. We may need to raise additional funds sooner than we anticipate if we choose to expand more rapidly than we presently anticipate. We may require additional capital for the further development of our product candidates. Additional capital may not be available when we need it, or on terms acceptable to us or at all. We have no committed source of additional capital. If adequate capital is not available to us on a timely basis, we may be required to significantly delay, limit, reduce or terminate our research and development programs or the commercialization of product candidates, if approved, or be unable to continue or expand our operations, or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition, results of operations, and growth prospects and cause the price of our common stock to decline. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a common stockholder. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures, or declaring dividends. If we raise additional funds through collaborations, strategic alliances, or licensing arrangements with pharmaceutical partners, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs, or product candidates, or grant licenses on terms that may not be favorable to us. Global credit and financial market conditions ~~and inflation~~ could negatively impact the value of our portfolio of cash equivalents and our ability to meet our financing objectives. Our cash and cash equivalents are generally maintained in highly liquid investments with original maturities of three months or less at the time of purchase. While, as of the date of this filing, we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since December 31, ~~2023~~ **2024** , no assurance can be given that deterioration in conditions of the global credit and financial markets ~~, including inflationary pressure,~~ would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. ~~Our operations are subject to the effects of rising inflation. The United States has experienced historically high levels of inflation over the last three years. According to the U. S. Department of Labor, the annual inflation rate for the United States was approximately 3. 4 % for the 12 months ended December 31, 2023, after being between 6. 5 %- 7. 0 % in each of 2022 and 2021. If the inflation rates continue at historically high levels, for example due to increases in the costs of labor and supplies, it may affect our expenses, such as employee compensation and research and development charges. Research and development expenses account for a significant portion of our operating expenses. Additionally, the U. S. is experiencing a continuing workforce shortage, which in turn has created a very competitive wage environment that may increase our operating costs. To the extent inflation results in further interest rate increases and has other adverse effects on the market, inflation may adversely affect our consolidated financial condition and results of operations or business prospects. Risks Related to the Ownership of Our Common Stock and Warrants~~ We do not know whether a sufficient market will continue to develop for our securities or what the market price of our securities will be, and, as a result, it may be difficult for investors to sell shares of our common stock ~~or outstanding warrants~~ . If a market for our common stock is not sustained, it may be difficult to sell shares of our common stock at an attractive price or at all. ~~Similarly, if an active and stable market for our outstanding warrants is not sustained, it may be difficult to sell such warrants at an attractive price or at all. The trading market for our securities may lack adequate size, liquidity or price transparency.~~ We cannot predict the prices at which our common stock ~~or warrants~~ will trade ~~. Moreover, features of our warrants, such as our redemption right or the 9. 9 % ownership limitation on exercisability, may affect the trading price of such warrants~~ . It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors, and, as a result of these and other factors, the price of our ~~trading securities~~ **common stock** may fall. The market price of our common stock has historically been highly volatile, and we expect it to continue to be volatile, which could result in substantial losses for investors who purchase our shares. The market price of our common stock has historically been highly volatile. For example, the closing price of our common stock has fluctuated from a low of $ ~~12~~ **2** . ~~64~~ **27** to a high of $ ~~30~~ **35** . ~~11~~ **08** over the 12 months preceding the filing date of this Annual Report on Form 10- K. Some of the factors that may cause the market price of our common stock to fluctuate include: ● the success of existing or new competitive products or technologies; ● the timing and results of clinical studies for our current product candidates and any future product candidates that we may develop; ● failure or discontinuation of any of our product development and research programs; ● results of preclinical studies, clinical studies, or regulatory approvals of product candidates of our competitors, or announcements about new research programs or product candidates of our competitors; ● regulatory or legal developments in the United States and other countries; ● developments or disputes concerning patent applications, issued patents, or other proprietary rights; ● the recruitment or departure of key personnel; ● the level of expenses related to any of our research programs, clinical development programs, or product candidates that we may develop; ● the results of our efforts to develop additional product candidates or products; ● actual or anticipated changes in estimates as to financial results or development timelines; ● announcement or expectation of additional financing efforts; ● sales of our common stock by us, our insiders, or other stockholders **; ● Short selling of our stock, in which a seller sells shares of our stock that the seller has borrowed from a third party, which often occurs when a short seller expects the price of our common stock to decline** ; ● variations in our financial results or those of companies that are perceived to be similar to us; ● changes in estimates or recommendations by securities analysts, if any, that cover our stock; ● market conditions in the pharmaceutical and biotechnology sectors; ● general economic, industry, and market conditions; and ● securities litigation, regardless of merit. In recent years, the stock market in general, Nasdaq, and the markets for early- stage companies and pharmaceutical and biotechnology companies have experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose

stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company' s securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we are currently and may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management' s attention and resources from our business. ~~Hedging arrangements relating to our warrants may affect the value and volatility of our common stock. In order to hedge their financial positions, certain warrant holders may enter into hedging transactions with respect to our common stock, may unwind or adjust hedging transactions and / or may purchase or sell large blocks of our common stock in one or more market transactions. The effect, if any, of these activities on the trading price of our common stock will depend in part on market conditions and cannot be known in advance, but any of these activities could adversely affect the value and price volatility of our common stock. The trading price for our warrants may bear little or no relationship to traditional valuation methods, or to the market price of our common stock, and therefore the trading price of the warrants may fluctuate significantly. The trading price of our warrants may have little or no relationship to, and may be significantly lower, or at times higher, than the price that would otherwise be established using traditional indicators of value, such as our future prospects and those of our industry in general; future potential revenues, earnings, cash flows, and other financial and operating information, or multiples thereof; market prices of securities and other financial and operating information of companies engaged in drug development activities similar to ours; and the views of research analysts. Potential investors should not buy warrants in the open market unless they are willing to take the risk that the trading price of the warrants could fluctuate and decline significantly. In order for warrant holders to recover the value of an investment in the shares of common stock received upon exercise of a warrant (after taking into account the bonus share fraction during any bonus share period) at the exercise price, the value of such shares of common stock must be more than the exercise price of the warrants. In addition, we may redeem all unexercised warrants at our sole option at any time on or after April 15, 2024, and upon meeting certain other conditions. If we redeem unexercised warrants, they will cease to be outstanding after the redemption date, they will cease to trade, and they will have no value.~~ If securities analysts do not publish research or reports about our business, or we are the subject of negative publicity, the price of our stock could decline. The trading market for our securities depends, in part, on the research and reports that securities or industry analysts publish about us or our business. We do not control these analysts. If one or more of the analysts who cover us downgrade our stock or publish inaccurate or unfavorable evaluations of our company or our stock, the price of our securities could decline. If one or more of these analysts cease coverage of our company or fail to publish reports covering our company regularly, our stock may lose visibility in the market, which in turn could cause the price of our securities to decline. In addition, if we are the subject of negative publicity, whether from an analyst, academic, social media, industry group or the general or financial press, the price of our securities may decline. ~~Short selling — also known as " shorting, " " selling short " or " going short " — refers to the sale of a security or financial instrument that the seller has borrowed from a third party. A short seller hopes to profit from a decline in the value of the securities they are shorting. As it is in the short seller' s financial interest for the price of our stock to decline, some short sellers may publish misrepresentations, falsehoods or mischaracterizations regarding our business operations, including our pre- clinical or clinical results, that are intended to create and spread negative publicity about us. Since negative information can travel fast in the media, short seller activity can lead to a sudden, sharp decline in the market value of the market price of our securities, which is sometimes known as a " short attack. " Issuers, like us, with securities that have historically had limited trading volumes and relatively high volatility, together with the challenges of engaging in new and complex scientific endeavors, can make us particularly vulnerable to such short seller attacks. Short selling may also lead to fluctuations of our stock price, particularly if other investors holding " long " positions in our common stock seek to counter short selling activity by purchasing additional shares, thus making it more difficult and more expensive for short sellers to profit. No assurances can be made that declines in the market price of our common stock will not occur in the future in connection with such activity.~~ General Risk Factors If we are unable to maintain effective internal controls, our business, financial position, and results of operations could be adversely affected. As a **smaller reporting company, our independent registered** public **accounting firm is not** ~~company, we are subject to reporting and other obligations under the Exchange Act including the requirements of Section 404 (a) of the Sarbanes- Oxley Act (" SOX "), which require~~ **required** ~~annual management assessments of the effectiveness~~ **to conduct, and has not conducted, an audit** of our internal control over financial reporting. **It is possible that, had** ~~Section 404 (b) of SOX also requires~~ our independent ~~auditors to attest to,~~ **registered public accounting firm conducted** ~~and~~ **an audit** ~~report on, the effectiveness~~ of our internal control over financial reporting **, such firm might have identified material weaknesses and deficiencies that we have not identified. If we or our independent auditors discover a material weakness, the disclosure of that fact, even if quickly remedied, could adversely affect the market price and trading liquidity of our common stock, cause investors to lose confidence in our financial reporting and generally materially adversely impact our business and financial condition** . The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation to meet the detailed standards under the rules. During testing, our management may identify material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by SOX. These reporting and other obligations place significant demands on our management and administrative and operational resources, including accounting resources. Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with accounting principles generally accepted in the U. S. Any failure to maintain effective internal controls, or if our independent registered public accounting firm is unable to attest to the effectiveness of our internal control over financial reporting, could have an adverse effect on our business, financial position, and results of operations. Anti-

takeover provisions in our charter documents and Delaware law may prevent or delay removal of incumbent management or a change of control. Anti- takeover provisions of our amended and restated certificate of incorporation and amended and restated bylaws and Delaware law may have the effect of deterring or delaying attempts by our stockholders to remove or replace management, engage in proxy contests and effect changes in control. ~~The~~ **Key** provisions of our **current** charter documents include: ● a classified board so that only one of the three classes of directors on our Board of Directors (the " Board ") is elected each year; ● elimination of cumulative voting in the election of directors; ● procedures for advance notification of stockholder nominations and proposals; ● the ability of the Board to amend our bylaws without stockholder approval; and ● the ability of the Board to issue up to 10, 000, 000 shares of preferred stock without stockholder approval upon the terms and conditions and with the rights, privileges and preferences as the Board may determine. In addition, as a Delaware corporation, we are subject to Delaware law, including Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years following the date that the stockholder became an interested stockholder unless certain specific requirements are met as set forth in Section 203. These provisions, alone or together, could have the effect of deterring or delaying changes in incumbent management, proxy contests or changes in control. Our amended and restated bylaws provide that the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Laws of 1933, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our amended and restated bylaws provide that the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act of 1933. While the Delaware courts have determined that such choice of forum provisions are valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions. In such instance, we would expect to vigorously assert the validity and enforceability of the exclusive forum provisions of our amended and restated bylaws. This may require significant additional costs associated with resolving such action in other jurisdictions and there can be no assurance that the provisions will be enforced by a court in those other jurisdictions. These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage these types of lawsuits. Furthermore, the enforceability of similar choice of forum provisions in other companies' certificates of incorporation or bylaws 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 exclusive- forum provision contained in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could harm our business. As of December 31, ~~2023~~ **2024**, we had aggregate federal net operating loss carryforwards of approximately $ ~~158~~ **205** . ~~7~~ **5** million, which begin to expire in 2029. Under Section 382 of the Internal Revenue Code of 1986, as amended, changes in our ownership may limit the amount of our net operating loss carryforwards that could be utilized annually to offset our future taxable income, if any. This limitation would generally apply in the event of a cumulative change in ownership of our company of more than 50 % within a rolling three- year period. Any such limitation may significantly reduce our ability to utilize our net operating loss carryforwards and tax credit carryforwards. Any such limitation, whether as the result of past offerings, sales of our common stock by our existing stockholders, the issuance of shares of common stock as a result of the exercise of warrants or additional sales of our common stock by us in the future could have a material adverse effect on our results of operations in future years. We have not completed a study to assess whether an ownership change for purposes of Section 382 has occurred. We may sell additional equity or debt securities to fund our operations, and have outstanding securities exercisable for our common stock, which may result in dilution to our stockholders and impose restrictions on our business. In order to raise additional capital to support our operations, we may sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock which could result in dilution our stockholders. We cannot assure you that we will be able to sell shares or other securities in any other offering at a price per share that is equal to or greater than the price per share paid by investors in prior offerings, and investors purchasing our shares or other securities in the future could have rights superior to existing shareholders. The price per share at which we sell additional shares of our common stock or securities convertible into or exchangeable for our common stock in future transactions may be higher or lower than the price per share in prior offerings. You may also be diluted upon the exercise of outstanding stock options as of December 31, ~~2023~~ **2024** to purchase approximately ~~3~~ **4** . ~~0~~ **5** million shares of our common stock at a weighted average price of $ **20.** 15 ~~. 13~~ per share ~~,~~ **and** the future issuance of up to approximately ~~2~~ **1** . ~~9~~ **0** million compensatory equity awards authorized under our 2018 Omnibus Incentive Plan ~~, and the potential issuance of up to 25. 3 million shares of our common stock from exercises of our outstanding warrants, initially issued in January 2024~~ . The issuance of such additional shares of common stock or the perception that issuances could occur, could result in significant downward pressure on our stock price. The estimates and judgments we make, or the assumptions on which we rely, in preparing our consolidated financial statements could prove inaccurate. Our consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the U. S. The preparation of these consolidated financial statements requires us to make estimates and judgments that affect the reported amounts of our assets, liabilities and expenses, the amounts of charges accrued by us and related disclosure of contingent assets and liabilities. Such estimates and judgments include development expenses, valuation of stock- based awards and income tax. We base our estimates on historical experience, facts and circumstances known to us and on various other assumptions that we believe to be reasonable under the circumstances. We cannot provide assurances, however, that our estimates, or the assumptions underlying them, will not change over time or otherwise prove inaccurate. If this is the case, we may be required to restate our consolidated financial statements, which could, in turn, subject us to securities class action litigation. Defending against such potential litigation relating to a restatement of our consolidated financial statements would be expensive and would require significant attention and resources of our management. Moreover, our insurance to cover

our obligations with respect to the ultimate resolution of any such litigation may be inadequate. As a result of these factors, any such potential litigation could have a material adverse effect on our financial results and cause our stock price to decline, which could in turn subject us to securities class action litigation.