Risk Factors Comparison 2024-03-28 to 2023-03-30 Form: 10-K

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

Our business, prospects, financial condition or results of operations could be materially adversely affected by any of the risks and uncertainties set forth below, as well as in any amendments or updates reflected in subsequent filings with the Securities and Exchange Commission (the " SEC "). In assessing these risks, you should also refer to other information contained in this report, including our financial statements and related notes. Risks Related to our Operations and to Development, Marketing, Commercialization and Regulation of Our Product Candidates We have incurred losses since inception, we anticipate that we will incur continued losses for the foreseeable future. We require additional financing to accomplish our long- term business plan and failure to obtain necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our operations. We have experienced net losses and negative cash flows from operating activities since our inception and have an accumulated deficit of $ ~~95~~ **108** . ~~8~~ **3** million as of December 31, ~~2022~~ **2023** . It is possible we will never generate revenue or profit. Although we are exploring financing opportunities and carefully monitoring the capital markets, we do not yet have any commitments for additional financing and may not be successful in our efforts to raise additional funds. There can be no assurances that additional financing will be available to us on satisfactory terms, or at all. If we are unable to raise sufficient additional capital (which is not assured at this time, particularly as a result of recent depressed capital market conditions), our long- term business plan may not be accomplished, and we may be forced to cease, reduce, or delay operations. For more information about our liquidity and capital resources, see **" Liquidity and Capital Resources " in** Part II, Item 7 ~~"~~ **.** Management' s Discussion and Analysis of Financial Condition and Results of Operations ~~— Liquidity and Capital Resources~~ . ~~"~~ Raising additional capital may cause dilution to existing stockholders, restrict our operations or require us to relinquish rights to our technologies. Existing stockholders could suffer dilution or be negatively affected by fixed payment obligations we may incur if we raise additional funds through the issuance of additional equity securities or debt. Furthermore, these securities may have rights senior to those of our common stock and could contain covenants or protective rights that would restrict our operations and potentially impair our competitiveness, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. If we need to secure additional financing, such additional fundraising efforts may divert our management and research efforts from our day- to- day activities, which may adversely affect our ability to develop and commercialize our product candidates. **Adverse global economic conditions could have a negative effect on our business, results of operations and financial condition and liquidity. A general slowdown in the global economy, including a recession, or in a particular region or industry, an increase in trade tensions with U. S. trading partners, inflation or a tightening of the credit markets could negatively impact our business, financial condition and liquidity. Adverse global economic conditions have from time to time caused or exacerbated significant slowdowns in the industries and markets in which we operate, which have adversely affected our business and results of operations. Macroeconomic weakness and uncertainty also make it more difficult for us to accurately forecast revenue, gross margin and expenses, and may make it more difficult to raise or refinance debt.** Worldwide economic and social instability could adversely affect our revenue, financial condition, or results of operations. The health of the global economy, and the credit markets and the financial services industry in particular, as well as the stability of the social fabric of our society, affects our business and operating results. **The general economic** ~~For example, the credit~~ and ~~financial~~ **capital** ~~markets~~ **market** ~~may be~~ **conditions, both in the U. S. and worldwide, have been volatile in the past and at times have** adversely affected **our access to capital** ~~by the turmoil in the banking section in the wake of the failure of Silicon Valley Bank~~ and **increased** ~~measures taken in response thereto. If~~ the **cost of capital. The capital and** credit markets ~~are~~ **may** not ~~favorable, we may~~ be ~~unable~~ **available** to **support future capital raising activity** ~~raise additional financing when needed or~~ on favorable terms. **If economic conditions decline, our future cost of equity or debt capital and access to the capital markets could be adversely affected.** Our ~~customers~~ **vendors and development partners** may experience financial difficulties or be unable to borrow money to fund their operations, which may adversely impact their ability to purchase our products or to pay for our products on a timely basis, if at all ~~. In addition, adverse economic conditions, such as recent supply chain disruptions and labor shortages and persistent inflation, have impacted, and may continue to adversely impact our suppliers' ability to provide our manufacturer with materials and components, which may negatively impact our business~~ . These economic conditions make it more difficult for us to accurately forecast and plan our future business activities. **Conditions in the banking system and financial markets, including the failure of banks and financial institutions, could have an adverse effect on our operations and financial results. Actual events involving limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions, transactional counterparties or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds or other similar risks, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023 and March 12, 2023, the Federal Deposit Insurance Corporation took control and was appointed receiver of Silicon Valley Bank, Signature Bank and Silvergate Capital Corp, respectively, after each bank was unable to continue their operations. Since then, additional financial institutions have experienced similar failures and have been placed into receivership. It is possible that other banks will face similar difficulty in the future. Although we do not maintain any deposit accounts, credit agreements or letters of credit with any financial institution currently in receivership, we are unable to predict the extent or nature of the impacts of these evolving circumstances at this time. If, for example, other banks and financial institutions enter**

receivership or become insolvent in the future in response to financial conditions affecting the banking system and financial markets, our ability to access our existing cash, cash equivalents and investments may be threatened. While it is not possible at this time to predict the extent of the impact that the failure of these financial institutions or the high market volatility and instability of the banking sector could have on economic activity and our business in particular, the failure of other banks and financial institutions and the measures taken by governments, businesses and other organizations in response to these events could adversely impact our business, financial condition and results of operations. We are ~~initially~~ developing DA- 1241 for the treatment of ~~NASH~~ **MASH**, an indication for which there ~~are no~~ **is only one** approved ~~products~~ **product**. This makes it difficult to predict the timing and costs of the clinical development of DA- 1241 ~~and, if applicable, DA- 1726, for the treatment of NASH~~. Our ~~research and development~~ **R & D** efforts **are** ~~will be~~ focused in part on developing DA- 1241 for the treatment of ~~NASH~~ **MASH**, an indication for which there ~~are no~~ **is only one** approved ~~products~~ **product**. The regulatory approval process for novel product candidates **,** such as DA- 1241 for ~~NASH~~ **MASH ,** can be more expensive and take longer than for other, better known or extensively studied product candidates. ~~As~~ **In addition to Madrigal Pharmaceuticals' approved product,** other companies are in later stages of clinical trials for their potential ~~NASH~~ **MASH** therapies, **and** we expect that the path for regulatory approval for ~~NASH~~ **MASH** therapies may continue to evolve in the near term as these other companies refine their regulatory approval strategies and interact with regulatory authorities. Such evolution may impact our future clinical trial designs, including trial size and endpoints, in ways that we cannot predict today. Our anticipated development costs would likely increase if development of DA- 1241 or any future product candidate is delayed because ~~we are required by~~ the FDA **requires us** to perform studies or trials in addition to, or different from, those that we currently anticipate. Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to predict the timing or amount of any increase in our anticipated development costs. We may be required to make significant payments under the 2022 License Agreement. We ~~will~~ have ~~acquired~~ exclusive rights (other than in the Republic of Korea) to DA- 1241 and DA- 1726 for the specific indications provided in the 2022 License Agreement. Under the 2022 License Agreement, in consideration for the license, we made an upfront payment of 2, 200 shares of our Series A Convertible Preferred Stock. As additional consideration for the license, we are required to pay Dong- A milestone payments upon the achievement of specified regulatory milestones and milestone payments upon the achievement of specified commercial milestones. Commencing on the first commercial sale of licensed products, we are obligated to pay royalties of single- digit percentages on annual net sales of the products covered by the license. If milestone or other non- royalty obligations become due, we may not have sufficient funds available to meet our obligations, which ~~will~~ **may** materially adversely affect our business operations and financial condition. ~~37Even~~ -- **Even** if we obtain favorable clinical results, we may not be able to obtain regulatory approval for, or successfully commercialize DA- 1241 and DA- ~~1726We~~ -- **1726 We** are not permitted to market DA- 1241 or DA- 1726 in the ~~United States~~ **U. S.** until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries. As a condition to submitting an NDA to the FDA for DA- 1241 or DA- 1726, we must successfully complete several clinical trials demonstrating efficacy and safety. DA- 1241 and DA- 1726 may not be successful in clinical trials or receive regulatory approval. Further, DA- 1241 and DA- 1726 may not receive regulatory approval even if ~~it is~~ **they are** successful in clinical trials. Obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process that typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, the policies or 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. Our development activities could be harmed or delayed by a partial shutdown of the U. S. government, including the FDA. We have not obtained regulatory approval for any product candidate **,** and it is possible that DA- 1241 and DA- 1726 will never obtain regulatory approval. The FDA may delay, limit or deny approval of DA- 1241 or DA- 1726 for many reasons, including, among others: ● the results of our clinical trials may not meet the level of statistical or clinical significance required by the FDA for marketing approval; ● the FDA may disagree with the number, design, size, conduct or implementation of our clinical trials; ● the FDA may not approve the formulation, labeling or specifications of DA- 1241 or DA- 1726; ● the FDA may require that we conduct additional clinical trials; ● the contract research organizations (" CROs ") or the clinical investigators that we retain to conduct our clinical trials may take actions outside of our control that materially adversely impact our clinical trials; ● we, our CROs or clinical investigators may fail to perform in accordance with the FDA' s good clinical practice (" GCP ") requirements; ● the FDA may disagree with our interpretation of data from our preclinical studies and clinical trials; ● the FDA may find deficiencies with the manufacturing processes or facilities of third- party manufacturers with which we contract; or ● the policies or regulations of the FDA may significantly change in a manner that renders our clinical data insufficient for approval or may require that we amend or submit new clinical protocols. In addition, similar reasons may cause the EMA or other regulatory authorities to delay, limit or deny approval of DA- 1241 or DA- 1726 outside the ~~United States~~ **U. S**. Any of these factors, many of which are beyond our control, could jeopardize our ability to obtain regulatory approval for and successfully market DA- 1241 and DA- 1726. Alternatively, even if we obtain regulatory approval, that approval may be for indications or patient populations that are not as broad as we intend or desire or may require labeling that includes significant use or distribution restrictions or safety warnings. We may also be required to perform additional, unanticipated clinical trials to obtain approval or be subject to additional post marketing testing requirements to maintain regulatory approval. In addition, regulatory authorities may withdraw their approval of a product **,** or the FDA may require a risk evaluation and mitigation strategy (" REMS ") for a product, which could impose restrictions on ~~its~~ **our** distribution. Any of the foregoing scenarios could materially harm the commercial prospects for our product candidates. ~~38We~~ **We** may not be able to successfully obtain regulatory or marketing approval for, or successfully commercialize, any of our product candidates. Although we currently have no drug product for sale and may never be able to develop marketable drug products, our business depends heavily on the successful clinical development ~~(for our pharmaceutical~~

~~drug products)~~ , regulatory approval and commercialization of our ~~drug~~ **product** candidates. The clinical trials of our product candidates are, and the manufacturing and marketing of our product candidates will be, subject to extensive and rigorous review and regulation by government authorities in the ~~United States~~ **U. S.** and in other countries where we intend to test and, if approved, market any product candidate. Before obtaining regulatory approvals for the commercial sale of any product candidate as a pharmaceutical product, we must successfully meet a number of critical developmental milestones, including: ● developing dosages that will be well- tolerated, safe and effective; ● completing the development and scale- up to permit manufacture of our product candidates in commercial quantities and at acceptable costs; ● demonstrating through pivotal clinical trials that the product candidate is safe and effective in patients for the intended indication; ● establishing commercial manufacturing capabilities or making arrangements with third- party manufacturers; and ● obtaining and maintaining exclusive rights, including patent and trade secret protection and non- patent exclusivity for our product candidates. The time necessary to achieve these developmental milestones for any individual product candidate is long and uncertain, and we may not successfully complete these milestones for any product candidates that we may develop. We are continuing to test and develop our product candidates and may explore possible design or formulation changes to address safety, efficacy, manufacturing efficiency and performance issues to the extent any arise. The design of a clinical trial may be able to determine whether its results will support approval of a product, and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced or completed. There is no assurance that we will be able to design and complete a clinical trial to support marketing approval. Moreover, nonclinical and clinical data are often susceptible to multiple interpretations and analyses. A number of companies in the pharmaceutical and biotechnology industries have experienced significant setbacks in advanced clinical trials, even after promising results in earlier trials. We may not be able to complete development of any product candidates that demonstrate safety and efficacy and that will have a commercially reasonable treatment and storage period. If we are unable to complete development of DA- 1241, DA- 1726 or any other product candidates that we may develop, we will not be able to commercialize and earn revenue from them. The regulatory review and approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time- consuming and inherently unpredictable, our business will be substantially harmed. Of the large number of drugs in development in the ~~United States~~ **U. S.** , only a small percentage receive FDA regulatory approval and are commercialized in the ~~United States~~ **U. S** . We are not permitted to market DA- 1241, DA- 1726 or any other product candidate as a pharmaceutical drug in the ~~United States~~ **U. S.** until we receive approval of an NDA from the FDA, or in any foreign countries until we receive the requisite approval from such countries or jurisdictions, such as the ~~marketing authorization application, or~~ MAA ~~,~~ in the European Union from the European Medicines Agency ~~, or~~ **(“** EMA **”)** . Successfully completing clinical trials and obtaining approval of an NDA is a complex, lengthy, expensive and uncertain process, and the FDA, or a comparable foreign regulatory authority, may delay, limit or deny approval of an NDA for many reasons, including, among others: ● disagreement with the design or implementation of our clinical trials; ~~39~~ ● disagreement with the sufficiency of our clinical trials; ● failure to demonstrate the safety and efficacy of the product candidate for the proposed indications; ● failure to demonstrate that any clinical and other benefits of the product candidate outweigh their safety risks; ● a negative interpretation of the data from our nonclinical studies or clinical trials; ● ~~deficiencies in the manufacturing or control processes or failure of third- party manufacturing facilities with which our contracts for clinical and commercial supplies to comply with current Good Manufacturing Practice requirements, or cGMPs; ● deficiencies in the harvesting and processing of botanical raw materials under Good Agricultural and Collection Processes, or GACPs, or the inability to demonstrate that the final product is capable of being therapeutically consistent, as applicable to botanical drug products, as applicable;~~ ● insufficient data collected from clinical trials or changes in the approval requirements that render our nonclinical and clinical data insufficient to support the filing of an NDA or to obtain regulatory approval; or ● changes in clinical practice in ~~or~~ **our** approved products available for the treatment of the target patient population that could have an impact on the indications that we are pursuing for our product candidates. The FDA or a comparable foreign regulatory authority may also require more information, including additional nonclinical or clinical data to support approval, which may delay or prevent approval and our commercialization plans, or cause us to abandon the development program. Even if we obtain regulatory approval, our product candidates may be approved for fewer or more limited indications than we request, such approval may be contingent on the performance of costly post- marketing clinical trials, or we may not be allowed to include the labeling claims necessary or desirable for the successful commercialization of such product candidate. Product candidates may cause undesirable side effects that could delay or prevent their marketing approval, limit the commercial profile of an approved label, or result in significant negative consequences following marketing approval, if any, including marketing withdrawal. Undesirable side effects caused by any of our product candidates that we may develop or acquire could cause us or the FDA or other regulatory authorities to interrupt, delay or halt our clinical trials and could result in more restrictive labels or the delay or denial of marketing approval by the FDA or other regulatory authorities of such product candidates. Results of our clinical trials could reveal a high and unacceptable severity and prevalence of these or other side effects. In such an event, our trials could be suspended or terminated **,** and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. In addition, any drug- related side effects could affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. Any of these occurrences may harm our business, financial condition and prospects significantly. Further, clinical trials by their nature utilize a sample of the potential patient population. With a limited number of patients, rare and severe side effects of our product candidates may only be uncovered with a significantly larger number of patients exposed to the product candidate. If our product candidates receive marketing approval and we or others identify undesirable side effects caused by such product candidates (or any other similar drugs) after such approval, a number of potentially significant negative consequences could result, including: ● regulatory authorities may withdraw or limit their approval of such product candidates; ● regulatory authorities may require the addition of labeling statements, such as a" boxed" warning or a contraindication; ● we may be required to recall the product, change the

way such product candidates are distributed or administered, conduct additional clinical trials or change the labeling of the product candidates; ● regulatory authorities may require a Risk Evaluation and Mitigation Strategy (REMS) plan to mitigate risks, which could include medication guides to be distributed to patients, physician communication plans, or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools; ● we may be subject to regulatory investigations and government enforcement actions; ● we may be subject to fines, injunctions or the imposition of civil or criminal penalties; ● we may decide to remove such product candidates from the marketplace after they are approved; ● the product may be rendered less competitive **,** and sales may decrease; ~~40~~ ● we could be sued and held liable for injury caused to individuals exposed to or taking ~~its~~ **our** product candidates; and ● our reputation may suffer. We believe that any of these events could prevent us from achieving or maintaining market acceptance of the affected product candidates and could substantially increase the costs of commercializing our product candidates, if approved, and significantly impact our ability to successfully commercialize our product candidates and generate revenues. Delays in our clinical trials may lead to a delay in the submission of marketing approval applications and jeopardize our ability to potentially receive approvals and generate revenues from the sale of our products. We may experience delays in **ongoing and planned** clinical trials. We do not know whether planned clinical trials will begin or enroll subjects on time, need to be redesigned or be completed on schedule, if at all. Clinical trials may be delayed, suspended or terminated for a variety of reasons, such as: ● delay or failure in reaching agreement with the FDA or a comparable foreign regulatory authority on a trial design that we are able to execute; ● delay or failure in obtaining authorization to commence a trial or inability to comply with conditions imposed by a regulatory authority regarding the scope or design of a clinical trial; ● inability, delay or failure in identifying and maintaining a sufficient number of trial sites, many of which may already be engaged in competing clinical trial programs; ● issues with the manufacture of drug substance for use in clinical trials; ● delay or failure in recruiting and enrolling suitable subjects to participate in a trial; ● delay or failure in having subjects complete a trial or return for post- treatment follow- up; ● clinical sites and investigators deviating from trial protocol, failing to conduct the trial in accordance with regulatory requirements, or dropping out of a trial; ● delay or failure in reaching agreement on acceptable terms with prospective ~~clinical research organizations, or~~ CROs ~~,~~ and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● delay or failure in obtaining ~~institutional review board, or~~ IRB ~~,~~ approval to conduct a clinical trial at each site; ● delays resulting from negative or equivocal findings of the Data Safety Monitoring Board ~~, or~~ **(“** DSMB **”)** , if any; ● ambiguous or negative results; ● decision by the FDA, a comparable foreign regulatory authority, or recommendation by a DSMB to suspend or terminate clinical trials at any time for safety issues or for any other reason; ● conflicts affecting clinical trial sites and regions where clinical trials are being completed; ● lack of adequate funding to continue the product development program; or ● changes in governmental regulations or requirements. Any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of our product candidates. We may develop DA- 1241 and DA- 1726, and potentially future product candidates, in combination with other therapies, which exposes us to additional risks. We may develop DA- 1241 and DA- 1726 and future product candidates in combination with one or more currently approved therapies. Even if any product candidate we develop were to receive marketing approval or be commercialized for use in combination with other existing therapies, we would continue to be subject to the risks that the FDA or similar regulatory authorities outside of the ~~United States~~ **U. S.** could revoke approval of the therapy used in combination with our product candidate or that safety, efficacy, manufacturing or supply issues could arise with these existing therapies. This could result in our own products being removed from the market or being less successful commercially. We may also evaluate DA- 1241 and DA- 1726 or any other future product candidates in combination with one or more other therapies that have not yet been approved for marketing by the FDA or similar regulatory authorities outside of the ~~41United States~~ **U. S** . We will not be able to market and sell DA- 1241 and DA- 1726 or any product candidate we develop in combination with any such unapproved therapies that do not ultimately obtain marketing approval. If the FDA or similar regulatory authorities outside of the ~~United States~~ **U. S.** do not approve these other drugs or revoke their approval of, or if safety, efficacy, manufacturing, or supply issues arise with, the drugs we choose to evaluate in combination with DA- 1241 and DA- 1726 or any other product candidate we develop, we may be unable to obtain approval of or market DA- 1241 and DA- 1726 or any other product candidate we develop. Enrollment and retention of patients in clinical trials is an expensive and time- consuming process and could be made more difficult or rendered impossible by multiple factors outside our control, including difficulties in identifying patients with ~~NASH~~ **MASH** and significant competition for recruiting such patients in clinical trials. Identifying and qualifying patients to participate in our clinical trials is critical to our success. We may encounter delays in enrolling, or be unable to enroll, a sufficient number of patients to complete any of our clinical trials, and even once enrolled we may be unable to retain a sufficient number of patients to complete any of our trials. In particular, as a result of the inherent difficulties in diagnosing ~~NASH~~ **MASH** and the significant competition for recruiting patients with ~~NASH~~ **MASH** in clinical trials, there may be delays in enrolling the patients we need to complete clinical trials on a timely basis, or at all. This risk may be more significant for us than other companies conducting clinical trials for the treatment of patients with ~~NASH~~ **MASH** because we **are** ~~plan to enroll~~ **enrolling** only patients with a biopsy- confirmed diagnosis of ~~NASH~~ **MASH** in our ~~planned~~ clinical trials. Factors that may generally affect patient enrollment include: ● the size and nature of the patient population; ● the number and location of clinical sites we enroll; ● competition with other companies for clinical sites or patients; ● the eligibility and exclusion criteria for the trial; ● the design of the clinical trial; ● inability to obtain and maintain patient consents; ● risk that enrolled participants will drop out before completion; and ● competing clinical trials and clinicians’ and patients’ perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs that may be approved for the indications we are investigating. In addition, if any significant

adverse events or other side effects are observed in any of our future clinical trials, it may make it more difficult for us to recruit patients to our clinical trials and patients may drop out of our trials, or we may be required to abandon the trials or our development efforts of one or more product candidates altogether. Our inability to enroll a sufficient number of patients for our clinical trials would result in significant delays, which would increase our costs and have an adverse effect on our company. We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do. The development and commercialization of new products is highly competitive. Our future success depends on our ability to demonstrate and maintain a competitive advantage with respect to the development and commercialization of our product candidates. Our objective is to develop and commercialize new products with superior efficacy, convenience, tolerability and safety. In many cases, the products that we commercialize will compete with existing, market- leading products. Many of our potential competitors have significantly greater financial, manufacturing, marketing, drug development, technical and human resources than we do. Large pharmaceutical companies, in particular, have extensive experience in clinical testing, obtaining regulatory approvals, recruiting patients and in manufacturing pharmaceutical products. In particular, these companies have greater experience and expertise in securing government contracts and grants to support their ~~research and development~~ **R & D** efforts, conducting testing and clinical trials, obtaining regulatory approvals to market products, manufacturing such products on a broad scale and marketing approved products. These companies also have significantly greater research and marketing capabilities than we do and may also have products that have been approved or are in late stages of development, and have collaborative arrangements in our target markets with leading companies and research institutions. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel compounds or to in- license novel compounds that could make the product that we develop obsolete. As a result of all of these factors, our competitors may succeed in obtaining patent protection and / or FDA approval or ~~42discovering~~ -- **discovering** , developing and commercializing products before, or more effectively than, we do. In addition, any new product that competes with an approved product must demonstrate compelling advantages in efficacy, convenience, tolerability and safety in order to overcome price competition and to be commercially successful. If we are not able to compete effectively against potential competitors, our business will not grow **,** and our financial condition and operations will suffer. ~~T2DThere~~ --- **There is only one approved treatment of MASH, Madrigal Pharmaceuticals' thyroid hormone receptor beta agonist. However, various therapeutics are used off- label for the treatment of MASH, including vitamin E (an antioxidant), insulin sensitizers (e. g., metformin, pioglitazone), antihyperlipidemic agents (e. g., gemfibrozil), pentoxifylline and ursodeoxycholic acid (UDCA). There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of MASH, including Novo Nordisk' s GLP1 agonist semaglutide, Eli Lilly' s GLP1R and GIP dual agonist tirzepatide, Akero Therapeutics' s FGF21 analog efruxifermin, 89 Bio' s FGF21 analog pegaozafermin, Inventiva' s pan- peroxisome proliferator- activated receptor agonist, Boston Pharmaceuticals and Roche' s fibroblast growth factor 21 analogs, and farnesoid X receptor agonists from Intercept Pharmaceuticals Inc., among others. Additional pharmaceutical and biotechnology companies with product candidates in development for the treatment of MASH include AstraZeneca plc, Altimmune Inc., Boehringer Ingelheim GmbH, Bristol- Myers Squibb Company, Durect Corporation, Galectin Therapeutics Inc., Galmed Pharmaceuticals Ltd., Immuron Ltd., Ionis Pharmaceuticals, Inc., Islet Sciences, Inc., MediciNova, Inc., NGM Biopharmaceuticals, Inc., NuSirt Sciences Inc., Pfizer Inc., Viking Therapeutics, Inc. and Zydus Pharmaceuticals (USA) Inc. MASH is a complex disease and we believe that it is unlikely that any one therapeutic option will be optimal for every MASH patient. Obesity Due to the growing overweight and obesity epidemic and consumer demand, there are many competitors in the field of obesity treatment. Obesity treatments range from behavioral modification to drugs and medical devices, and surgery, generally as a last resort. If DA- 1726 were approved for obesity, our primary competition in the obesity treatment market would currently be from approved and marketed products, including semaglutide (WEGOVY ®) and tirzepatide (Zepbound ®). Further competition could arise from products currently in development, including among others, with GLP1R / GCGR dual agonists, Boehringer Ingelheim, Merck / Hanmi Pharmaceutical, AstraZeneca, Altimmune, Innovent Biologics / Eli Lilly, Carmot and D & D Pharma; with GLP1R / GCGR / GIP triple agonists, Hanmi Pharmaceutical and Eli Lilly; Amgen with its GLP- 1 agonist / GIP antagonist antibody; and Novo Nordisk with Amylin and Amylin- GLP- 1 combination. To the extent any of our product candidates are approved for obesity, the commercial success of our product will also depend on our ability to demonstrate benefits over the then- prevailing standard of care. Finally, morbidly obese patients sometimes undergo a gastric bypass procedure, with salutary effects on the many co- morbid conditions of obesity. T2DM There** are a number of large pharmaceutical and biotechnology companies that currently market and sell products or are pursuing the development of products for ~~T2D~~ **T2DM** . Some of these competitive products and therapies are based on scientific approaches that are the same as or similar to our approach and others are based on entirely different approaches. 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. ~~NASHThere are currently no medications approved for the treatment of NASH. However, various therapeutics are used off- label for the treatment of NASH, including vitamin E (an antioxidant), insulin sensitizers (e. g., metformin, pioglitazone), antihyperlipidemic agents (e. g., gemfibrozil), pentoxifylline and ursodeoxycholic acid (UDCA). There are several product candidates in Phase 3 or earlier clinical or preclinical development for the treatment of NASH, including Madrigal Pharmaceuticals, Inc.' s THR beta agonist (resmetirom), Novo Nordisk' s GLP1 agonist (semaglutide), Akero Therapeutics' s FGF21 analog (efruxifermin), 89 Bio' s FGF21 analog (pegaozafermin and Inventiva' s pan- PPAR agonist (lanifibranor), as well as FXR agonists from Intercept Pharmaceuticals Inc. (obeticholic acid), Novartis AG (tropifexor, nidufexor), Metacrine (MET409, MET642), Terns Pharmaceuticals (TERN- 101), Gilead Sciences, Inc. (cilofexor) and Enanta Pharmaceuticals, Inc. (EDP- 305). ObesityDue to the growing overweight and obesity epidemic and consumer demand, there are many competitors in~~

~~the field of obesity treatment. Obesity treatments range from behavioral modification, to drugs and medical devices, and surgery, generally as a last resort. If DA- 1726 were approved for obesity, our primary competition in the obesity treatment market would currently be from approved and marketed products, including, liragluitde (SAXENDA ®), semaglutide (WEGOVY ®), phentermine / topiramate (QSYMIA ®), naltrexone / bupropion (CONTRAVE ®) and orlistat (XENICAL ® / ALLI ®). Further competition could arise from products currently in development, including Lilly' s GLP- 1 / GIP receptor dual agonist (tierzepatide),~~ Our commercial success depends upon attaining significant market acceptance of our product candidates, if approved, among hospitals, physicians, patients and healthcare payors. Even if we obtain regulatory approval for any of our product candidates that we may develop or acquire in the future, the product may not gain market acceptance among hospitals, physicians, health care payors, patients and the medical community. Market acceptance of any of our product candidates for which we receive regulatory approval depends on a number of factors, including: ● the clinical indications for which the product candidate is approved; ● acceptance by major operators of hospitals, physicians and patients of the product candidate as a safe and effective treatment, particularly the ability of our product candidates to establish themselves as a new standard of care in the treatment paradigm for the indications that we are pursuing; ● the potential and perceived advantages of our product candidates over alternative treatments as compared to the relative costs of the product candidates and alternative treatments; ● the willingness of physicians to prescribe, and patients to take, a product candidate that is based on a botanical source; ● the prevalence and severity of any side effects with respect to our product candidates, and any elements that may be imposed by the FDA under a REMS program that could discourage market uptake of the products; ● the availability of adequate reimbursement and pricing for any approved products by third party payors and government authorities; ● inability of certain types of patients to take our product; ~~43~~ ● demonstrated ability to treat patients and, if required by any applicable regulatory authority in connection with the approval for target indications, to provide patients with incremental cardiovascular disease benefits, as compared with other available therapies; ● the relative convenience and ease of administration of our product candidates, including as compared with other treatments available for approved indications; ● limitations or warnings contained in the labeling approved by the FDA; ● availability of alternative treatments already approved or expected to be commercially launched in the near future; ● the effectiveness of our sales and marketing strategies; ● guidelines and recommendations of organizations involved in research, treatment and prevention of various diseases that may advocate for alternative therapies; ● the willingness of patients to pay out- of- pocket in the absence of third- party coverage; ● physicians or patients may be reluctant to switch from existing therapies even if potentially more effective, safe or convenient; ● efficacy, safety, and potential advantages compared to alternative treatments; ● the ability to offer our product for sale at competitive prices; ● the willingness of the target patient population to try new therapies and of physicians to prescribe these therapies; ● any restrictions on the use of our product together with other medications; ● interactions of our product with other medicines patients are taking; and ● the timing of market introduction of our products as well as competitive products. There may be delays in getting our product candidates, if approved, on hospital or insurance formularies or limitations on coverages that may be available in the early stages of commercialization for newly approved drugs. If any of our product candidates are approved but fail to achieve market acceptance among hospitals, physicians, patients or health care payors, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition and results of operations. Even if we are able to commercialize a future pharmaceutical drug candidate, the profitability of such product candidate will likely depend in significant part on third- party reimbursement practices, which, if unfavorable, would harm our business. Our ability to commercialize a drug successfully will depend in part on the extent to which coverage and adequate reimbursement will be available from government health administration authorities, private health insurers and other organizations. Government authorities and third- party payors, such as private health insurers and health maintenance organizations, decide which medications they will pay for and establish reimbursement levels. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that drug companies provide them with predetermined discounts from list prices and are challenging the prices charged for medical products. We cannot be sure that coverage will be available for any product candidate that we commercialize and, if coverage is available, whether the level of reimbursement will be adequate. Assuming we obtain coverage for our product candidates, if approved, by a third- party payor, the resulting reimbursement payment rates may not be adequate or may require co- payments that patients find unacceptably high. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third- party payors to reimburse all or part of the costs associated with their prescription drugs. Patients are unlikely to use a product candidate, if approved, unless coverage is provided **,** and reimbursement is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate reimbursement is critical to new product acceptance. If reimbursement is not available or is available only to limited levels, we may not be able to successfully commercialize any product candidate for which we obtain marketing approval. There may be significant delays in obtaining reimbursement for newly approved drugs, and coverage may be more limited than the purposes for which a product candidate is approved by the FDA or similar regulatory authorities outside the ~~United States~~ **U. S** . Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers ~~its~~ **our** costs, including research, development, manufacture, sale and distribution. Interim reimbursement levels for a new product, if applicable, may also not be sufficient to cover our costs and may not be made ~~44permanent~~ -- **permanent** . Reimbursement rates may vary according to the use of the product and the clinical setting in which it is used, may be based on reimbursement levels already set for lower cost medicines and may be incorporated into existing payments for other services. Net prices for products may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of medicines from countries where they may be sold at lower prices than in the ~~United States~~ **U. S** . Third- party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement policies. However, no uniform policy requirement for coverage and

reimbursement for drug products exists among third- party payors in the ~~United States~~ **U. S** . Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time- consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and profitable payment rates from both government- funded and private payors for any approved products that we develop could have an adverse effect on our operating results, our ability to raise capital needed to commercialize products and our overall financial condition. Product liability lawsuits against us could cause us to incur substantial liabilities and could limit commercialization of any product candidate that we may develop. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk if we commercially sell any product that we may develop. Product liability claims might be brought against us by patients, healthcare providers or others selling or otherwise coming into contact with any of our products or future product candidate during product testing, manufacturing, marketing or sale. For example, we may be sued on allegations that a product candidate caused injury or that the product is otherwise unsuitable. Any such product liability claims may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, including as a result of interactions with alcohol or other drugs, negligence, strict liability, and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend against claims that our product caused injuries, we could incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in: ● decreased demand for any product candidate that we are developing; ● injury to our reputation and significant negative media attention; ● withdrawal of clinical trial participants; ● increased FDA warnings on product labels; ● significant costs to defend the related litigation; ● substantial monetary awards to trial participants or patients; ● distraction of management' s attention from our primary business; ● loss of revenue; ● the inability to commercialize any product candidate that we may develop; ● the removal of a product from the market; and ● increased insurance costs. If we or our third- party manufacturers fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have an adverse effect on the success of our business. Our ~~research and development~~ **R & D** activities involve the controlled use of potentially hazardous substances, including chemical and biological materials, by us and our third- party manufacturers. Our manufacturers are subject to federal, state and local laws and regulations in the ~~United States~~ **U. S.** and abroad governing laboratory procedures and the use, manufacture, storage, handling and disposal of medical and hazardous materials. Although we believe that our manufacturers' procedures for using, handling, storing and disposing of these materials comply with legally prescribed standards, we cannot completely eliminate the risk of contamination or injury resulting from medical or hazardous ~~45materials~~ -- **materials** . As a result of any such contamination or injury, we may incur liability or local, city, state or federal authorities may curtail the use of these materials and interrupt our business operations. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from medical or hazardous materials. Although we maintain workers' compensation insurance to cover us for costs and expenses **,** we may incur due to injuries to our employees resulting from the use of hazardous materials, this insurance may not provide adequate coverage against potential liabilities. Compliance with applicable environmental, health and safety laws and regulations ~~is~~ **are** expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, prospects, financial condition or results of operations ~~.~~ We rely and will continue to rely on collaborative partners regarding the development of our research programs and product candidates. We are and expect to continue to be dependent on collaborations with partners relating to the development and commercialization of our existing and future research programs and product candidates. In particular, we rely on Dong- A to provide services with respect to our development of DA- 1241 and DA- 1726. In addition, we **have** had, have and will continue to have discussions on potential partnering opportunities with various pharmaceutical ~~and medical device~~ companies. If we fail to enter into or maintain collaborative agreements on reasonable terms or at all, our ability to develop our existing or future research programs and product candidates could be delayed, the commercial potential of our products could change, and our costs of development and commercialization could increase. Our dependence on collaborative partners subjects it to a number of risks, including, but not limited to, the following: ● We may not be able to control the amount or timing of resources that collaborative partners devote to our research programs and product candidates; ● We may be required to relinquish significant rights, including intellectual property, marketing and distribution rights; ● We rely on the information and data received from third parties regarding our research programs and product candidates and will not have control of the process conducted by the third party in gathering and composing such data and information. We may not have formal or appropriate guarantees from our contract parties with respect to the quality and the completeness of such data; ● A collaborative partner may develop a competing product either by itself or in collaboration with others, including one or more of our competitors; ● Our collaborative partners' willingness or ability to complete their obligations under our collaboration arrangements may be adversely affected by business combinations or significant changes in a collaborative partner' s business strategy; and / or ● We may experience delays in, or increases in the costs of, the development of our research programs and product candidates due to the termination or expiration of collaborative ~~research and development~~ **R & D** arrangements. If ~~we are unable to establish sales and marketing capabilities to market and sell our product candidates, if they are approved for such marketing, we may be unable to generate any revenue. In order to market and sell our product candidates in development, we currently intend to build and develop our own sales, marketing and distribution operations. Although our management team has previous experience with such efforts for pharmaceutical products, there can be no assurance that we will be successful in building these operations. The establishment and development of our own commercial sales and marketing teams to discuss any products we may develop will be expensive and time- consuming and could delay any product launch. If we are unable to establish adequate sales, marketing and distribution capabilities, we may not be able to generate product revenue and may not become profitable. We will also be~~

~~competing with many companies that currently have extensive and well- funded sales and marketing operations. If any of our product candidates are approved, we may be unable to compete successfully against these more established companies. 46If~~ , in the future, we are unable to establish sales and marketing capabilities or to selectively enter into agreements with third parties to sell and market our product candidates, we may not be successful in commercializing our product candidates if and when they are approved. We do not have a sales or marketing infrastructure and have no experience in the sale, marketing or distribution of pharmaceutical products. To achieve commercial success for any approved product for which we retain sales and marketing responsibilities, we must either develop a sales and marketing organization or outsource these functions to other third parties. In the future, we may choose to build a focused sales and marketing infrastructure to sell some of our product candidates if and when they are approved. There are risks involved both with establishing our own sales and marketing capabilities and with entering into arrangements with third parties to perform these services. For example, recruiting and training a sales force is expensive and time consuming and could delay any product launch. If the commercial launch of a product candidate for which we recruit a sales force and establish marketing capabilities is delayed or does not occur for any reason, we would have prematurely or unnecessarily incurred these commercialization expenses. This may be costly, and our investment would be lost if we cannot retain or reposition our sales and marketing personnel. Factors that may inhibit our efforts to commercialize our product candidates on our own include: ● our inability to recruit and retain adequate numbers of effective sales and marketing personnel; ● the inability of sales personnel to obtain access to physicians or persuade adequate numbers of physicians to prescribe any future pharmaceutical products; and ● unforeseen costs and expenses associated with creating an independent sales and marketing organization. If we enter into arrangements with third parties to perform sales, marketing and distribution services, our product revenue or the profitability of these product revenue may be lower than if we were to market and sell any products that we develop ourselves. In addition, we may not be successful in entering into arrangements with third parties to sell and market our product candidates or may be unable to do so on terms that are favorable to us. We may have little control over such third parties, and any of them may fail to devote the necessary resources and attention to sell and market our products effectively. If we do not establish sales and marketing capabilities successfully, either on our own or in collaboration with third parties, we will not be successful in commercializing our product candidates. Any product candidate for which we obtain marketing approval could be subject to marketing restrictions or withdrawal from the market, and we may be subject to penalties if we fail to comply with regulatory requirements or if we experience unanticipated problems with our products. Any pharmaceutical product candidate for which we obtain marketing approval will be subject to continual requirements of and review by the FDA and other regulatory authorities. These requirements include submissions of safety and other post- marketing information and reports, registration and listing requirements, cGMP requirements, quality assurance and corresponding maintenance of records and documents and requirements regarding the distribution of samples to physicians and recordkeeping. Even if marketing approval of a product candidate is granted, the approval may be subject to limitations on the indicated uses for which the product may be marketed or to the conditions of approval, or contain requirements for costly post- marketing testing and surveillance to monitor the safety or efficacy of the medicine. The FDA closely regulates the post- approval marketing and promotion of drugs to ensure that they are marketed only for the approved indications and in accordance with the provisions of the approved labeling. The FDA imposes stringent restrictions on manufacturers' communications regarding off-label use and if we do not market our products for their approved indications, we may be subject to enforcement action for off-label marketing and / or promotion. In addition, later discovery of previously unknown problems with our products, manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things: ● restrictions on such products, manufacturers or manufacturing processes; ● restrictions on the labeling, marketing, distribution or use of a product; ● requirements to conduct post- approval clinical trials; ● warning or untitled letters; ~~47~~ ● withdrawal of the products from the market; ● refusal to approve pending applications or supplements to approved applications that we submit; ● recall of products; ● fines, restitution or disgorgement of profits or revenue; ● suspension or withdrawal of marketing approvals for the drug products; ● refusal to permit the import or export of our products; ● product seizure; and ● injunctions or the imposition of civil or criminal penalties. We or any potential collaborator may never receive regulatory approval to market our product candidates outside of the ~~United States~~ **U. S** . The activities associated with the development and commercialization of pharmaceutical drugs are subject to comprehensive regulation by the FDA, other regulatory agencies in the ~~United States~~ **U. S.** and by comparable authorities in other countries. Failure to obtain regulatory approval for our product candidates will prevent us or any potential collaborator from commercializing our product candidates as pharmaceutical drugs. We have not received regulatory approval to market any of our product candidates in any jurisdiction, and we do not expect to obtain FDA or any other regulatory approvals to market any of our product candidates for the foreseeable future, if at all. The process of obtaining regulatory approvals is expensive, often takes many years, if approval is obtained at all, and can vary substantially based upon the type, complexity and novelty of the product candidates involved. We may seek to avail ourselves of mechanisms to expedite and / or reduce the cost for development or approval of any of our product candidates or product candidates we may pursue in the future, such as fast track designation or orphan drug designation, but such mechanisms may not actually lead to a faster or less expensive development or regulatory review or approval process. We may seek fast track designation, priority review, orphan drug designation, or accelerated approval for any product candidate we may pursue in the future. For example, if a drug is intended for the treatment of a serious or life- threatening condition and the drug demonstrates the potential to address unmet medical needs for this condition, the drug sponsor may apply for FDA fast track designation. However, the FDA has broad discretion with regard to these mechanisms, and even if we believe a particular product candidate is eligible for any such mechanism, ~~it~~ **we** cannot assure you that the FDA would decide to grant it. Even if we obtain fast track or priority review designation or pursue an accelerated approval pathway, we may not experience a faster and / or less costly development process, review or approval compared to conventional FDA procedures. The FDA may withdraw a particular designation if it believes that the designation is no longer supported by data from our clinical development program. Current and future legislation may

increase the difficulty and cost ~~to~~ **of** ~~obtain~~ **obtaining** marketing approval of and ~~commercialize~~ **commercialization of** our product candidates and affect the prices we may obtain. In the ~~United States~~ **U. S.** and some foreign jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates, restrict post- approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. See the section titled " ~~Item 1 — Business — Government~~ Regulation " **in** above **Item 1. Business** . Legislative and regulatory proposals have been made to expand post- approval requirements and restrict sales and promotional activities for pharmaceutical products. We cannot be sure whether additional legislative changes will be enacted, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on the marketing approvals, if any, of our product candidates may be. In addition, increased scrutiny by the U. S. Congress of the FDA' s approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post- marketing conditions and other requirements. ~~48Governments~~ -- **Governments** outside the ~~United States~~ **U. S.** tend to impose strict price controls, which may adversely affect our revenues, if any. In some countries, particularly the countries of the European Union, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after the receipt of marketing approval for a product. To obtain reimbursement or pricing approval in some countries, we may be required to conduct a clinical trial that compares the cost- effectiveness of ~~its~~ **our** product candidate to other available therapies. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be harmed, possibly materially. Our relationships with healthcare providers and third- party payors will be subject to applicable anti- kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings, among other penalties and consequences. Healthcare providers and third- party payors will play a primary role in the recommendation and prescription of any product candidate for which we obtain marketing approval. Our arrangements with third- party 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 candidate for which we obtain marketing approval. Restrictions and obligations under applicable federal and state healthcare laws and regulations are noted in ~~the section~~ " ~~Item 1 — Business — Government~~ Regulation " **in** above **Item 1. Business** . Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. 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 it, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion of products from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. We are subject to U. S. and certain foreign export and import controls, sanctions, embargoes, anti- corruption laws, and anti- money laundering laws and regulations. Compliance with these legal standards could impair ~~its~~ **our** ability to compete in domestic and international markets. We can face criminal liability and other serious consequences for violations which can harm ~~its~~ **our** business. We are subject to export control and import laws and regulations, including the U. S. Export Administration Regulations, U. S. Customs regulations, various economic and trade sanctions regulations administered by the U. S. Treasury Department' s Office of Foreign Assets Controls, the U. S. Foreign Corrupt Practices Act of 1977, as amended, the U. S. domestic bribery statute contained in 18 U. S. C. § 201, the U. S. Travel Act, the USA PATRIOT Act, and other state and national anti- bribery and anti- money laundering laws in the countries in which we conduct activities. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and other partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We may engage third parties for clinical trials outside of the ~~United States~~ **U. S.** to sell our products abroad and / or to obtain necessary permits, licenses, patent registrations, and other regulatory approvals. We have direct or indirect interactions with officials and employees of government agencies or government- affiliated hospitals, universities, and other organizations. We can be held liable for the corrupt or other illegal activities of our employees, agents, contractors, and other partners, even if it does not explicitly authorize or have actual knowledge of such activities. Our violations of the laws and regulations described above may result in substantial civil and criminal fines and penalties, imprisonment, the loss of export or import privileges, debarment, tax reassessments, breach of contract and fraud litigation, reputational harm, and other consequences. ~~49Our~~ -- **Our** ability to use our NOLs to offset future taxable income may be subject to certain limitations. In general, under Section 382 of Internal Revenue Code of 1986, as amended (the " Code "), a corporation that undergoes an" ownership change" is subject to limitations on ~~its~~ **our** ability to utilize ~~its~~ **our** carryforwards to offset future taxable income. Our existing **net operating loss (“** NOL **”)** carryforwards ~~, or NOLs,~~ were subject to limitation arising from an ownership change related to the Dong- A Financing and the **underwritten public offering we closed on in November 2022 (the “ 2022** Public Offering **”)** . Future changes in our stock ownership, some of which are outside of our control, could result in further ownership changes under Section 382 of the Code. There is also a risk that due to regulatory changes, such as suspensions on the use of ~~NOLs~~ - **NOL carryforwards** , or other unforeseen reasons, our existing and any future ~~NOLs~~ - **NOL carryforwards** could expire or otherwise be unavailable to offset future income tax liabilities. Tax matters, including the changes in corporate tax rates, disagreements with taxing authorities and imposition of new taxes could impact ~~our~~ **the** results of **our** operations and financial condition. We are subject to income and other taxes in the ~~United States~~ **U. S.** and our operations, plans and results are affected by tax and other initiatives. On December 22, 2017, comprehensive changes to the Code were signed into law,

informally titled the Tax Cuts and Jobs Act (the " Tax Act "). The Tax Act included significant changes that could materially impact the taxation of corporations, like us, including among other things, changes to the corporate income tax rate, limitation of the tax deduction for interest expense to business interest income plus 30 % of adjusted taxable income (except for certain small businesses), immediate deductions for certain new investments instead of deductions for depreciation expense over time, and modifying or repealing many business deductions and credits (including changes to the orphan drug tax credit and changes to the deductibility of research and experimental expenditures that will be effective in the future). The Tax Act also included a limitation of the deduction for net operating losses (" NOLs ") generated in tax years beginning after December 31, 2017 to 80 % of current year taxable income and the general elimination of carrybacks of NOLs generated in taxable years ending after December 31, 2017. However, the Coronavirus Aid, Relief, and Economic Security Act (" CARES Act ") signed into law ~~on~~ **in** March ~~27,~~ 2020, provided that NOLs generated in a taxable year beginning in 2018, 2019 ~~,~~ or 2020, may now be carried back five years. In addition, the 80 % taxable income limitation is temporarily removed, allowing NOLs to fully offset net taxable income. Notwithstanding the reduction in the corporate income tax rate, the overall impact of the Tax Act and any future tax reform is uncertain and our business and financial condition could be adversely affected. The impact of the Tax Act and any future tax reform on holders of our common stock is likewise uncertain and could be adverse. We are also subject to regular reviews, examinations, and audits by the IRS and other taxing authorities with respect to our taxes. Although we believe our tax estimates are reasonable, if a taxing authority disagrees with the positions we have taken, we could face additional tax liability, including interest and penalties. There can be no assurance that payment of such additional amounts upon final adjudication of any disputes will not have a material impact on our results of operations and financial position. We also need to comply with new, evolving or revised tax laws and regulations. The enactment of or increases in tariffs, or other changes in the application or interpretation of the Tax Act, or on specific products that we may ultimately sell or with which our products compete, may have an adverse effect on our business or on our results of operations. Inadequate funding for the FDA and other government agencies could hinder their 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 those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, the ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies on which the combined organization' s operations may rely, including those that fund ~~research and development~~ **R & D** activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new drugs to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last ~~50several~~ -- **several** years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, in our operations as a public company, 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. Federal legislation and actions by state and local governments may permit reimportation of drugs from foreign countries into the ~~United States~~ **U. S.** , including foreign countries where the drugs are sold at lower prices than in the ~~United States~~ **U. S.** , which could adversely affect our operating results. We may face competition for our product candidates, if approved, from cheaper alternatives sourced from foreign countries that have placed price controls on pharmaceutical products. The Medicare Modernization Act contains provisions that may change U. S. importation laws and expand pharmacists' and wholesalers' ability to import cheaper versions of an approved drug and competing products from Canada, where there are government price controls. These changes to U. S. importation laws will not take effect unless and until the Secretary of Health and Human Services **(" HHS ")** certifies that the changes will pose no additional risk to the public' s health and safety and will result in a significant reduction in the cost of products to consumers. ~~In July of~~ **On August 16,** ~~2021~~ **2022 ,** President Biden ~~issued~~ **signed into law the Inflation Reduction Act of 2022 (" IRA "), which, among other provisions, included several measures intended to lower the cost of prescription drugs and related healthcare reforms. Further, the Biden administration released** an **additional** executive order **on October 14, 2022, directing HHS** to **submit a report on how** ~~bolster health- care industry competition in~~ the ~~interest of~~ **Center for Medicare and Medicaid Innovation can be further leveraged to test new models for** lowering drug **costs** ~~prices. Among its proposals are a push~~ for **Medicare and Medicaid beneficiaries. It is unclear whether** ~~the~~ **these** ~~Food and Drug Administration to work with~~ **executive orders or similar policy initiatives will be implemented in the future. Individual** states **in the U. S. have also become increasingly active in passing legislation and implementing regulations designed** to ~~import~~ **control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts,** ~~prescription~~ **restrictions** ~~drugs~~ **on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation** from ~~Canada~~ **other countries and bulk purchasing** . It remains to be seen how ~~this~~ **these** ~~action~~ **actions** will affect **NeuroBo** ~~the Company~~ and the pharmaceutical industry as a whole. Risks Related to Dependence on Third Parties We have relied and will rely on third- party clinical research organizations (CROs) to conduct our preclinical studies and clinical trials. If these CROs do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed. We have relied upon and plan to continue to rely upon CROs and clinical data management organizations to monitor and manage data for our ongoing preclinical and clinical programs. Although we control only certain aspects of their activities, we are responsible for ensuring that each of our studies is conducted in accordance with the applicable protocol and legal, regulatory and scientific standards, and our reliance

on the CROs does not relieve us of our regulatory responsibilities. We also rely on third parties to conduct our preclinical studies in accordance with Good Laboratory Practice ~~, or~~ **(“** GLP ~~,~~ **”)** requirements and the Laboratory Animal Welfare Act of 1966 requirements. We, our CROs and our clinical trial sites are required to comply with regulations and current Good Clinical Practices ~~, or~~ **(“** GCP **”)** , and comparable foreign requirements to ensure that the health, safety and rights of patients are protected in clinical trials, and that data integrity is assured. Regulatory authorities ensure compliance with GCP requirements through periodic inspections of trial sponsors and trial sites. If we, any of our CROs or our clinical trial sites fail to comply with applicable GCP requirements, the clinical data generated in our clinical trials **,** or a specific site may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Our CROs are not our employees, and except for remedies available to us under our agreements with such CROs, we cannot control whether or not they devote sufficient time and resources to our ongoing clinical ~~and preclinical~~ programs. If CROs do not successfully carry out their contractual obligations or meet expected timelines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. As a result, our results of operations and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed. ~~51We~~ **We** rely on third parties to manufacture our product candidates and preclinical and clinical drug supplies. We have no experience manufacturing our product candidates on a large clinical or commercial scale and have no manufacturing facility. We currently have no plans to build our own clinical or commercial scale manufacturing capabilities. We currently work exclusively with Dong- A ~~ST~~ as the sole manufacturer for the production of DA- 1241 and DA- 1726. To meet our projected needs for clinical supplies to support our activities for DA- 1241 and DA- 1726 through regulatory approval and commercial manufacturing, Dong- A will need to provide sufficient scale of production for these projected needs. If any issues arise in the manufacturing and we are unable to arrange for alternative third- party manufacturing sources, we are unable to find an alternative third party capable of reproducing the existing manufacturing method or we are unable to do so on commercially reasonable terms or in a timely manner, we may not be able to complete development of our product candidates, or market or distribute them. Reliance on third- party manufacturers entails risks to which we would not be subject if we manufactured our product candidates and preclinical and clinical drug supplies, including: ● reliance on the third party for regulatory compliance and quality assurance; ● the possibility of breach of the manufacturing agreement by the third party because of factors beyond our control (including a failure to synthesize and manufacture our product candidates or any products that we may eventually commercialize in accordance with our specifications); ● the possibility of termination or nonrenewal of the agreement by the third party, based on our own business priorities, at a time that is costly or damaging to us; ● delay in, or failure to obtain, regulatory approval of any of our product candidates because of the failure by our third- party manufacturer to comply with cGMP or failure to scale up manufacturing processes; and ● current manufacturer and any future manufacturers may not be able to manufacture our product candidates at a cost or in quantities or in a timely manner necessary to make commercially successful products. If third- party manufacturers do not successfully carry out their contractual obligations or meet expected timelines or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols, regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates. We may engage in future acquisitions **, mergers** or in- licenses of technology that could disrupt our business, cause dilution to the organization' s stockholders and harm our financial condition and operating results. **We** ~~While we currently have no specific plans to acquire any other businesses or in- license any additional products or technology, we~~ may, in the future, make acquisitions or licenses of, or investments in, companies, products or technologies that we believe are a strategic or commercial fit with ~~its~~ **our** current product candidates and business or otherwise offer opportunities for us. In connection with these acquisitions **, mergers** or investments, the organization may: ● issue stock that would dilute ~~its~~ **our** stockholders' percentage of ownership; ● expend cash; ● incur debt and assume liabilities; and ● incur amortization expenses related to intangible assets or incur large and immediate write- offs. We also may be unable to find suitable acquisition **, merger** or license candidates and we may not be able to complete acquisitions **, mergers** or licenses on favorable terms, if at all. If we do complete an acquisition **, merger** or license, we cannot assure you that it will ultimately strengthen our competitive position or that it will not be viewed negatively by customers, financial markets or investors. Further, future acquisitions **, mergers** or licenses could also pose numerous additional risks to our operations, including: ● problems integrating the purchased or licensed business, products or technologies; ● increases to our expenses; ● the failure to have discovered undisclosed liabilities of the acquired or licensed asset or company; ● diversion of management' s attention from their day- to- day responsibilities; ● harm to our operating results or financial condition; ● entrance into markets in which we have limited or no prior experience; and ~~52~~ ● potential loss of key employees, particularly those of the acquired entity. We may not be able to complete one or more acquisitions **or mergers** or effectively integrate the operations, products or personnel gained through any such acquisition without a material adverse effect on our business, financial condition and results of operations. We may form or seek strategic alliances or enter into additional licensing arrangements in the future, and we may not realize the benefits of such alliances or licensing arrangements. We may form or seek strategic alliances, create joint ventures or collaborations or enter into additional licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our products and any future product candidates that we may develop. Any strategic alliance or collaboration may require us to incur non- recurring and other charges, increase our near and long- term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. Our likely collaborators include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the

development or commercialization of our products or any future product candidate. Our ability to generate revenues from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Collaborations involving our product candidates **,** or any future product candidate pose the following risks to us: ● collaborators have significant discretion in determining the efforts and resources that they will apply to these collaborations; ● collaborators may not perform their obligations as expected; ● collaborators may not pursue development and commercialization or may elect not to continue or renew development or commercialization programs based on clinical trial results, changes in the collaborator' s strategic focus or available funding or external factors such as an acquisition that diverts resources or creates competing priorities; ● collaborators may delay clinical trials, provide insufficient funding for a clinical trial program, stop a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new formulation of a product candidate for clinical testing; ● collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our product candidates if the collaborators believe that competitive products are more likely to be successfully developed or can be commercialized under terms that are more economically attractive; ● a collaborator with marketing and distribution rights to one or more product candidates may not commit sufficient resources to the marketing and distribution of any such product candidate; ● collaborators may not properly maintain or defend our intellectual property rights or may use our proprietary information in such a way as to invite litigation that could jeopardize or invalidate our proprietary information or expose us to potential litigation; ● collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability; ● disputes may arise between the collaborators and us that result in the delay or termination of the research, development or commercialization of our product candidate or that result in costly litigation or arbitration that diverts management' s attention and resources; ● we may lose certain valuable rights under circumstances identified in ~~its~~ **our** collaborations, including if ~~it~~ **we** ~~undergoes~~ -- **undergo** a change of control; ● collaborations may be terminated and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable product candidates; ● collaborators may learn about our discoveries and use this knowledge to compete with us in the future; ● the results of collaborators' preclinical or clinical studies could harm or impair other development programs; ● there may be conflicts between different collaborators that could negatively affect those collaborations and potentially others; ~~53~~ ● the number and type of our collaborations could adversely affect our attractiveness to future collaborators or acquirers; ● collaboration agreements may not lead to development or commercialization of our product candidate in the most efficient manner or at all. If our present or future collaborator were to be involved in a business combination, the continued pursuit and emphasis on our product development or commercialization program under such collaboration could be delayed, diminished or terminated; and ● collaborators may be unable to obtain the necessary marketing approvals. If future collaboration partners fail to develop or effectively commercialize our product candidates or any future product candidate for any of these reasons, such product candidate may not be approved for sale and our sales of such product candidate, if approved, may be limited, which would have an adverse effect on our operating results and financial condition. ~~If we are not able to establish new collaborations on commercially reasonable terms, we may have to alter our development and commercialization plans. We may selectively seek additional third- party collaborators for the development and commercialization of our product candidates. Our likely collaborators for any collaboration arrangements include large and mid- size pharmaceutical companies, regional and national pharmaceutical companies and biotechnology companies. If we enter into any such arrangements with any third parties, we will likely have limited control over the amount and timing of resources that our collaborators dedicate to the development or commercialization of our product candidates. Our ability to generate revenue from these arrangements will depend on our collaborators' abilities to successfully perform the functions assigned to them in these arrangements. We may be restricted under existing collaboration agreements from entering into future agreements on certain terms with potential collaborators. Collaborations are complex and time- consuming to negotiate and document. In addition, there have been a significant number of recent business combinations among large pharmaceutical companies that have resulted in a reduced number of potential future collaborators. We may not be able to negotiate collaborations on a timely basis, on acceptable terms, or at all. If we are unable to do so, we may have to curtail the development of the product candidate for which we are seeking to collaborate, reduce or delay our development program or one or more of our other development programs, delay our potential commercialization or reduce the scope of any sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we may not be able to further develop our product candidate or bring it to market and generate product revenue.~~ Our employees, principal investigators, CROs and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements, which could have a material adverse effect on our business. We are exposed to the risk that our employees, principal investigators, CROs and consultants may engage in fraudulent conduct or other illegal activity. Misconduct by these parties could include failures to comply with FDA regulations or similar regulations of comparable foreign regulatory authorities, to provide accurate information to the FDA or comparable foreign regulatory authorities, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable foreign regulatory authorities, to report financial information or data accurately or to disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or third-party misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result

in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent this activity, such as employee training, may not be effective in controlling ~~54unknown~~ -- **unknown** or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending such action or asserting our rights, those actions could have a significant impact on our business and results of operations, including the imposition of significant fines or other sanctions. Risks Related to Intellectual Property If we are unable to obtain and maintain sufficient intellectual property rights, our competitive position could be harmed. We depend on our ability to protect our proprietary technology. We rely on trade secret, patent, copyright and trademark laws, and confidentiality, licensing and other agreements with employees and third parties, all of which offer only limited protection. Our success depends in large part on our ability to obtain and maintain patent protection in the ~~United States~~ **U. S.** and other countries with respect to our proprietary technology and products. Where we have the right to do so under our license agreements, we seek to protect our proprietary position by filing patent applications in the ~~United States~~ **U. S.** and abroad related to our novel technologies and products that are important to our business. The patent positions of **pharmaceutical and** biotechnology ~~and pharmaceutical~~ companies generally are highly uncertain, involve complex legal and factual questions and have in recent years been the subject of much litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our patents, including those patent rights licensed to us by third parties, are highly uncertain. The steps we have taken to police and protect our proprietary rights may not be adequate to preclude misappropriation of our proprietary information or infringement of our intellectual property rights, both inside and outside the ~~United States~~ **U. S** . The rights already granted under any of our currently issued patents and those that may be granted under future issued patents may not provide us with the proprietary protection or competitive advantages that we are seeking. If we are unable to obtain and maintain patent protection for our technology and products, or if the scope of the patent protection obtained is not sufficient, our competitors could develop and commercialize technology and products similar or superior to ours, and our ability to successfully commercialize our technology and products may be adversely affected. With respect to patent rights, we do not know whether any of our pending patent applications for any of our product candidates will result in the issuance of patents that protect our technology or products, or which will effectively prevent others from commercializing competitive technologies and products. Our pending applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent **is** ~~issues~~ **issued** from such applications. Further, the examination process may require us or our licensors to narrow the claims, which may limit the scope of patent protection that may be obtained. Although our license agreement with Dong- A ~~ST~~ includes a number of issued patents that are exclusively licensed to us, the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, issued patents that we own or have licensed from third parties may be challenged in the courts or patent offices in the ~~United States~~ **U. S.** and abroad. Such challenges may result in the loss of patent protection, the narrowing of claims in such patents, or the invalidity or unenforceability of such patents, 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 for our technology and products. Protecting against the unauthorized use of our patented technology, trademarks and other intellectual property rights is expensive, difficult and may, in some cases, not be possible. In some cases, it may be difficult or impossible to detect third party infringement or misappropriation of our intellectual property rights, even in relation to issued patent claims, and proving any such infringement may be even more difficult. Laws and rulings by U. S. courts make it difficult to predict how patents will be issued or enforced in the biotechnology industry. Changes in either the patent laws or interpretation of the patent laws in the ~~United States~~ **U. S.** and other countries may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. There have been numerous changes to the patent laws and to the rules of the ~~United States Patent and Trademark Office, or~~ USPTO ~~,~~ which may have a significant impact on our ability to protect our technology and enforce our intellectual property rights. For example, the Leahy- Smith America Invents Act, which was signed into law in 2011, includes a transition from a" first- to- invent" system to a" first- to- file" system, and changes the way issued patents are challenged. Certain changes, ~~55such~~ -- **such** as the institution of inter partes review proceedings, came into effect ~~on~~ **in** September ~~16,~~ 2012. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and, if obtained, to enforce or defend them in litigation or post- grant proceedings, all of which could harm our business. Furthermore, the patent positions of companies engaged in the development and commercialization of biologics and pharmaceuticals are particularly uncertain. Two cases involving diagnostic method claims and" gene patents" have been decided by the Supreme Court. ~~On~~ **In** March ~~20,~~ 2012, the Supreme Court issued a decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc. ~~, or~~ **(“** Prometheus **”)** , a case involving patent claims directed to measuring a metabolic product in a patient to optimize a drug dosage amount for the patient. According to the Supreme Court, the addition of well- understood, routine or conventional activity such as" administering" or" determining" steps was not enough to transform an otherwise patent ineligible natural phenomenon into patent eligible subject matter. ~~On~~ **In** July ~~3,~~ 2012, the USPTO issued guidance indicating that process claims directed to a law of nature, a natural phenomenon or an abstract idea that do not include additional elements or steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied and the claim amounts to significantly more than the natural principle itself should be rejected as directed to non- statutory subject matter. ~~On~~ **In** June ~~13,~~ 2013, the Supreme Court issued its decision in Association for Molecular Pathology v. Myriad Genetics, Inc., ~~or~~ **(“** Myriad **”)** , a case involving patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2. Myriad held that isolated segments of naturally occurring DNA, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patent eligible subject matter, but that complementary DNA, which is an artificial construct that may be created from RNA transcripts of genes, may be patent eligible. We cannot assure you that our current patent protection and our efforts to seek patent protection for our technology and products will not be negatively impacted by the decisions described above, rulings in other cases or changes in guidance or procedures

issued by the USPTO. Moreover, although the Supreme Court has held in Myriad that isolated segments of naturally occurring DNA are not patent- eligible subject matter, certain third parties could allege that activities that we may undertake infringe other gene- related patent claims, and we may deem it necessary to defend against these claims by asserting non- infringement and / or invalidity positions, or pay to obtain a license to these claims. In any of the foregoing or in other situations involving third- party intellectual property rights, if we are unsuccessful in defending against claims of patent infringement, we could be forced to pay damages or be subjected to an injunction that would prevent us from utilizing the patented subject matter. Such outcomes could harm our business. We may not be able to protect or practice our intellectual property rights throughout the world. In jurisdictions where we have not obtained patent protection, competitors may use our intellectual property to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but where it is more difficult to enforce a patent as compared to the U. S. competitor products may compete with our product candidates, if approved, or any future product candidate in jurisdictions where we do not have issued or granted patents or where we issued or granted patent claims or other intellectual property rights are not sufficient to prevent competitor activities in these jurisdictions. The legal systems of certain countries, particularly certain developing countries, make it difficult to enforce patents and such countries may not recognize other types of intellectual property protection, particularly that relating to pharmaceuticals. This could make it difficult for us to prevent the infringement of ~~its~~ **our** patents or marketing of competing products in violation of our proprietary rights generally in certain jurisdictions. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert ~~its~~ **our** efforts and attention from other aspects of our business. The laws of some jurisdictions do not protect intellectual property rights to the same extent as the laws in the ~~United States~~ **U. S.** , and many companies have encountered significant difficulties in protecting and defending such rights in such jurisdictions. If we, or our licensors, encounter difficulties in protecting, or are otherwise precluded from effectively protecting, the intellectual property rights important for our business in such jurisdictions, the value of these rights may be diminished **,** and we may face additional competition from others in those jurisdictions. Many countries have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we, ~~56or~~ **or** any of our licensors, are forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position in the relevant jurisdiction may be impaired and our business and results of operations may be adversely affected. We may become involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming and unsuccessful. In addition to the possibility of litigation relating to infringement claims asserted against us, we may become a party to other patent litigation and other proceedings, including inter partes review proceedings, post- grant review proceedings, derivation proceedings declared by the USPTO and similar proceedings in foreign countries, regarding intellectual property rights with respect to our current or future technologies or product candidates or products. The cost to us of any patent litigation or other proceeding, even if resolved in our favor, could be substantial. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their substantially 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 could impair our ability to compete in the marketplace. Competitors may infringe or otherwise violate our intellectual property, including patents that may **be** ~~issue~~ **issued** to or be licensed by us. As a result, we may be required to file claims in an effort to stop third- party infringement or unauthorized use. Any such claims could provoke these parties to assert counterclaims against us, including claims alleging that we infringe their patents or other intellectual property rights. This can be prohibitively expensive, particularly for a company of our size, and time- consuming, and even if we are successful, any award of monetary damages or other remedy we may receive may not be commercially valuable. In addition, in an infringement proceeding, a court may decide that our asserted intellectual property is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our intellectual property does not cover ~~its~~ **our** technology. An adverse determination in any litigation or defense proceedings could put our intellectual property at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not ~~issuing~~ **being issued** . If the breadth or strength of our patent or other intellectual property rights is compromised or threatened, it could allow third parties to commercialize our technology or products or result in our inability to commercialize our technology and products without infringing third- party intellectual property rights. Further, third parties may be dissuaded from collaborating with us. Interference or derivation proceedings brought by the USPTO or its foreign counterparts may be necessary to determine the priority of inventions with respect to our patent applications, and we may also become involved in other proceedings, such as re- examination proceedings, before the USPTO or its foreign counterparts. Due to the substantial competition in the pharmaceutical space, the number of such proceedings may increase. This could delay the prosecution of our pending patent applications or impact the validity and enforceability of any future patents that we may obtain. In addition, any such litigation, submission or proceeding may be resolved adversely to us and, even if successful, may result in substantial costs and distraction to our management. 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. Moreover, intellectual property law relating to the fields in which we operate is still evolving and, consequently, patent and other intellectual property positions in our industry are subject to change and are often uncertain. We may not prevail in any of these suits or other efforts to protect ~~its~~ **our** technology, and the damages or other remedies awarded, if any, may not be commercially valuable. During the course of this type of litigation, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, the market price for the combined organization' s common stock could be significantly harmed. ~~57Third~~ -- **Third** parties may initiate legal proceedings alleging that we are infringing their intellectual property rights, the outcome of which would be uncertain and could have a

material adverse effect on the success of our business. Our commercial success depends upon our ability to develop, manufacture, market and sell our product candidates, and to use our proprietary technologies without infringing the proprietary rights of third parties. We may become party to, or threatened with, future adversarial proceedings or litigation regarding intellectual property rights with respect to our products and technology, including interference and various post grant proceedings before the USPTO or non- U. S. opposition proceedings. Third parties may assert infringement claims against us based on existing patents or patents that may be granted in the future. As a result of any such infringement claims, or to avoid potential claims, we may choose or be compelled to seek intellectual property licenses from third parties. These licenses may not be available on acceptable terms, or at all. Even if we are able to obtain a license, the license would likely obligate us to pay license fees or royalties or both, and the rights granted to us likely would be nonexclusive, which would mean that our competitors also could obtain licenses to the same intellectual property. Ultimately, we could be prevented from commercializing a product candidate or technology or be forced to cease some aspect of our business operations if, as a result of actual or threatened infringement claims, we are unable to enter into licenses of the relevant intellectual property on acceptable terms. Further, if we attempt to modify a product candidate or technology or to develop alternative methods or products in response to infringement claims or to avoid potential claims, we could incur substantial costs, encounter delays in product introductions or interruptions in sales. Ultimately, such efforts could be unsuccessful. Intellectual property litigation could cause us to spend substantial resources and distract our personnel from their normal responsibilities. Litigation or other legal proceedings relating to intellectual property claims, with or without merit, is unpredictable and generally expensive and time consuming and is likely to divert significant resources from our core business, including distracting our technical and management personnel from their normal responsibilities. 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. 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 and negatively impact our ability to raise additional funds. 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 adequately conduct such litigation or proceedings. 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. Accordingly, despite our efforts, we may not be able to prevent third parties from infringing upon or misappropriating or from successfully challenging our intellectual property rights. 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. We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers. Our employees and consultants have been previously employed at other biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although we are not aware of any claims currently pending against us, we may be subject to claims that these employees, or we have, inadvertently or otherwise used or disclosed trade secrets or other proprietary information or intellectual property of the former employers of our employees. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management. If we fail in defending such claims, in addition to paying money claims, we may lose valuable intellectual property rights or personnel. A loss of key personnel or their work product could hamper or prevent our ability to commercialize product candidates, which would adversely affect our commercial development efforts. ~~58Our~~ -- **Our** trade secrets are difficult to protect and 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 some of our technologies and product candidates, we also rely on trade secrets, including unpatented know-how, technology and other proprietary information, to maintain our competitive position. We seek to protect these trade secrets, 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, contract manufacturers, consultants, advisors and other third parties. We also enter into confidentiality, non- competition, non- solicitation, and invention assignment agreements with our employees and consultants that obligate them to assign to us any inventions developed in the course of their work for us. However, we cannot guarantee that we have executed these agreements with each party that may have or have had access to our trade secrets or that the agreements we have executed will provide adequate protection. Despite these efforts, any of these parties may breach the agreements and disclose our proprietary information, including our trade secrets, and we may not be able to seek patent protection on technology relating to our product candidates or obtain adequate remedies for such breaches. As a result, we may be forced to bring claims against third parties, or defend claims that they bring against us, to determine ownership of what we regard as our intellectual property. Monitoring unauthorized disclosure is difficult and we do not know whether the procedures that we have followed to prevent such disclosure are or will be adequate. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive and time- consuming, and the outcome is unpredictable. In addition, some courts inside and outside the ~~United States~~ **U. S.** may be less willing or unwilling to protect trade secrets. Furthermore, if any of the technology or information that we protect as trade secrets were to be lawfully obtained or independently developed by a competitor, 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, our competitive position would be **harmed.** ~~harmedObtaining~~ ------ **Obtaining** and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. Periodic maintenance fees on any issued patent are due to be paid to the USPTO, and foreign patent agencies in several stages over the

lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of ~~procedural~~ **procedurals** , documentary, fee payment and other requirements during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Non- compliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non- payment of fees and failure to properly legalize and submit formal documents. If we or our licensors fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market, which would have a material adverse effect on our business. Intellectual property rights do not necessarily address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. For example: ● others may be able to make product candidates that are similar to our product candidates but that are not covered by the claims of the patents that we own or have exclusively licensed; ● we or our future licensors or collaborators might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or have exclusively licensed; ● we or our future licensors or collaborators 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 intellectual property rights; ~~59~~ ● it is possible that our pending patent applications will not lead to issued patents; ● issued patents that we own or have exclusively licensed may be held invalid or unenforceable, as a result of legal challenges by our competitors; ● our competitors might conduct ~~research and development~~ **R & D** 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; and ● the patents of others may have an adverse effect on our business. Should any of these events occur, they could significantly harm our business, results of operations and prospects. Risks Related **to** Operations, Employee Matters and Managing Growth We currently have ~~no~~ **a small number of** employees and ~~a limited number of~~ consultants **,** and our future success depends on our ability to retain our executive officers and to attract, retain and motivate qualified personnel. Because of the specialized scientific nature of our business, we rely heavily on our ability to attract and retain qualified scientific, technical and managerial personnel. We are highly dependent upon current members of our management and scientific team ~~, each of whom serves as a consultant~~ . We intend to increase our technical and management staff as needs arise and supporting resources become available, but the loss of one or more of our senior executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the pharmaceutical field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the development of our business or to recruit suitable replacement personnel. We ~~will~~ **may** need to ~~grow~~ **increase** the size of our organization, and we may experience difficulties in managing this growth. As of ~~December 31~~ **March 25** , ~~2022~~ **2024** , we had ~~2~~ **eight** full- time employees ~~, 2 full- time consultants and 2 part- time consultants, all located in the United States. As of March 24, 2023, we had no full- time employees, 3 full- time consultants and 2 part- time consultants~~ . As our development and commercialization plans and strategies develop, or as a result of any future acquisitions, we ~~will~~ **may** need additional managerial, operational, development, sales, marketing, financial and other resources. Our management, personnel and systems currently in place ~~will~~ **may** not be adequate to support our future growth. Future growth would impose significant added responsibilities on our employees, including: ● managing our clinical trials effectively; ● identifying, recruiting, maintaining, motivating and integrating additional employees; ● managing our internal development efforts effectively while complying with our contractual obligations to licensors, contractors and other third parties; and ● improving our managerial, development, operational and finance ~~systemsAs~~ -- **systems As** our operations expand, we will need to manage additional relationships with various CROs, strategic partners, and other third parties. Our future financial performance and our ability to commercialize our product candidates and to compete effectively will depend, in part, on our ability to manage any future growth effectively. To that end, we must be able to manage our development efforts and clinical trials effectively and hire, train and integrate additional management, administrative, ~~research and development~~ **R & D** , and sales and marketing personnel. We may not be able to accomplish these tasks, and our failure to accomplish any of them could prevent us from successfully growing **NeuroBo** ~~the Company~~ . We intend to market our product candidates outside of the ~~United States~~ **U. S.** , and if we do, we will be subject to the risks of doing business outside of the ~~United States~~ **U. S** . Because we intend to market our product candidates, if approved, outside of the ~~United States~~ **U. S.** , our business is subject to risks associated with doing business outside of the ~~United States~~ **U. S** . Accordingly, our business and financial results in the future could be adversely affected due to a variety of factors, including: ● failure to develop an international sales, marketing and distribution system for our products; ~~60~~ ● changes in a specific country' s or region' s political and cultural climate or economic condition; ● unexpected changes in foreign laws and regulatory requirements; ● difficulty of effective enforcement of contractual provisions in local jurisdictions; ● inadequate intellectual property protection in foreign countries; ● inadequate data protection against unfair commercial use; ● trade- protection measures, import or export licensing requirements such as Export Administration Regulations promulgated by the ~~United States~~ **U. S.** Department of Commerce and fines, penalties or suspension or revocation of export privileges; ● the effects of applicable foreign tax structures and potentially adverse tax consequences; and ● significant adverse changes in foreign currency exchange rates. The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change, which could render our technologies and products obsolete or uncompetitive. The pharmaceutical industry is highly competitive and is subject to rapid and significant technological change, which could render certain of our products obsolete or uncompetitive. This is particularly true in the development of therapeutics for indications where new products and combinations of products are rapidly being developed that change the treatment paradigm for patients. There is no assurance

that our product candidates will be the most effective, have the best safety profile, be the first to market, or be the most economical to make or use. The introduction of competitive therapies as alternatives to our product candidates could dramatically reduce the value of those development projects or chances of successfully commercializing those product candidates, which could have a material adverse effect on our long- term financial success. We will compete with companies in the ~~United States~~ **U. S.** and internationally, including major pharmaceutical and chemical companies, specialized CROs, ~~research and development~~ **R & D** firms, universities and other research institutions. Many of our competitors have greater financial resources and selling and marketing capabilities, greater experience in clinical testing and human clinical trials of pharmaceutical products and greater experience in obtaining FDA and other regulatory approvals than we do. In addition, some of our competitors may have lower development and manufacturing costs. Risks Related to **our** Common Stock The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses **for holders** of our common stock. The trading price of our common stock **has been and** is likely **to continue** to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this" Risk Factors" section, these factors include: ● adverse results or delays in preclinical studies, clinical trials, regulatory decisions or the development status of our product candidates or any product candidates we may pursue in the future; ● our ability to raise sufficient additional funds necessary for the continued development of our product candidates whether through potential collaborative, partnering or other strategic arrangements or otherwise; ● the terms and timing of any future collaborative, licensing or other strategic arrangements that we may establish; ● ~~uncertainties created by our future management turnover; ●~~ our inability to comply with the minimum listing requirements of ~~the~~ Nasdaq ~~Stock Market LLC~~ ; ● the timing of achievement of, or failure to achieve, our, or any potential collaborator' s clinical, regulatory and other milestones, such as the commencement of clinical development, the completion of a clinical trial or the receipt of regulatory approval; ● decisions to initiate a clinical trial, not initiate a clinical trial, or terminate an existing clinical trial; ● adverse regulatory decisions, including failure to receive regulatory approval for our product candidates or regulatory actions requiring or leading to a delay or stoppage of any clinical trials; ● the commercial success of any product approved by the FDA or its foreign counterparts; ● changes in applicable laws, rules or regulations; ● adverse developments concerning our manufacturers, suppliers, collaborators and other third parties; ~~61~~ ● occurrence of health epidemics or contagious diseases, and potential effects on our business, clinical trial sites, supply chain and manufacturing facilities; ● our failure to commercialize our product candidates; ● the success of competitive drugs; ● if our patents covering our product candidates expire or are invalidated or are found to be unenforceable, or if some or all of our patent applications do not result in issued patents or result in patents with narrow, overbroad, or unenforceable claims; ● additions or departures of key scientific or management personnel; ● unanticipated safety concerns related to the use of any product candidates; ● our announcements or our competitor' s announcements regarding new products, enhancements, significant contracts, acquisitions or strategic partnerships and investments; ● the size and growth of our target markets; ● our, or companies perceived to be similar to us, failure to meet external expectations or management guidance; ● fluctuations in our quarterly financial results or the quarterly financial results of companies perceived to be similar to us; ● publication of research reports about us or our industry, recommendations, earning results or estimates or withdrawal of research coverage by securities analysts; ● changes in the market valuations of similar companies; ● changes in general economic, political and market conditions in any of the regions in which we conduct our business; ● changes in our capital structure or dividend policy, future issuances of securities, sales of common stock by officers, directors and significant stockholders or our incurrence of ~~additional~~ debt; ● trading volume of our common stock; ● changes in accounting practices and ineffectiveness of our internal controls; ● disputes, litigation or developments relating to proprietary rights; ● timing of milestones and royalty payments; and ● other events or factors, many of which are beyond our control. In addition, the stock market in general, Nasdaq, and the stock of biopharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company' s securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management' s attention and resources, which would harm our business, operating results or financial condition. We ~~are not currently in compliance with the continued listing requirements for Nasdaq. If the price of our common stock continues to trade below $ 1. 00 per share for a sustained period or we do not meet other continued listing requirements, our common stock may be delisted from the Nasdaq Capital Market, which could affect the market price and liquidity for our common stock and reduce our ability to raise additional capital. On February 8, 2023, we received written notice (the " Notification Letter ") from The Nasdaq Stock Market LLC (" Nasdaq ") notifying us that the Company was not in compliance with the minimum bid price requirements set forth in Nasdaq Listing Rule 5550 (a) (2) for continued listing on the Nasdaq Capital Market. Nasdaq Listing Rule 5550 (a) (2) requires listed securities maintain a minimum closing bid price of $ 1. 00 per share, and Nasdaq Listing Rule 5810 (c) (3) (A) provides that a failure to meet the minimum closing bid price requirement exists if the deficiency continues for a period of 30 consecutive business days. Based on the closing bid price of the Company' s common stock for the 30 consecutive business days prior to the date of the Notification Letter, the Company did not meet the minimum closing bid price requirement. To regain compliance, the closing bid price of the Company' s common stock must be at least $ 1. 00 per share for a minimum of 10 consecutive business days at any time prior to August 7, 2023. We continue to monitor the closing bid price of our common stock and consider our available options to resolve our noncompliance with the minimum bid price requirement. There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or we will otherwise be in compliance with other Nasdaq listing 62criteria. If we fail to regain compliance with the minimum bid requirement or to meet the other applicable continued listing requirements for the Nasdaq Capital Market in the future and Nasdaq may delist our common stock. Delisting from the NASDAQ could adversely affect our ability to raise~~

~~additional financing through the public or private sale of equity securities, would significantly affect the ability of investors to trade our securities and would negatively affect the value and liquidity of our common stock. Delisting could also have other negative results, including the potential loss of confidence by employees, the loss of institutional investor interest and fewer business development opportunities. If our common stock is delisted by the NASDAQ the price of our common stock may decline and our common stock may be eligible to trade on the OTC Bulletin Board, another over- the- counter quotation system, or on the pink sheets where an investor may find it more difficult to dispose of their common stock or obtain accurate quotations as to the market value of our common stock. Further, if we are delisted, we would incur additional costs under requirements of state " blue sky " laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. In addition, if our common stock is delisted from the NASDAQ Capital Market and the trading price remains below $ 5. 00 per share, trading in our common stock might also become subject to the requirements of certain rules promulgated under the Exchange Act, which require additional disclosure by broker- dealers in connection with any trade involving a stock defined as a " penny stock " (generally, any equity security not listed on a national securities exchange or quoted on NASDAQ that has a market price of less than $ 5. 00 per share, subject to certain exceptions). If we seek to implement a reverse stock split to remain listed on the NASDAQ Capital Market, the announcement or implementation of a reverse stock split could significantly negatively affect the price of our common stock. Additionally, in 2020, the SEC approved a previously proposed NASDAQ rule change to expedite delisting of securities with a closing bid price at or below $ 0. 10 for 10 consecutive trading days during any bid price compliance period and that have had one or more reverse stock splits with a cumulative ratio of 1 for 250 or more shares over the prior two- year period. In addition, if a company falls out of compliance with the $ 1. 00 minimum bid price after completing reverse stock splits over the immediately preceding two years that cumulatively result in a ratio of 1 for 250 shares, the company will not be able to avail itself of any bid price compliance periods under Rule 5810 (c) (3) (A), and NASDAQ will instead require the issuance of a Staff delisting determination. The company could appeal the determination to a hearings panel, which could grant the company a 180- day exception to remain listed if it believes the company would be able to achieve and maintain compliance with the bid price requirement. Following the exception, the company would be subject to the procedures applicable to a company with recurring deficiencies (NASDAQ Rule 5815 (d) (4) (B)). We continue to actively monitor our performance with respect to the listing standards and are considering available options to resolve the deficiency and regain compliance with the NASDAQ rules. There can be no assurance that we will be able to regain compliance with any deficiency, or maintain compliance even if we implement an option that regains our compliance. 63We~~ may enter into financing transactions that are dilutive to our stockholders, impose material restrictions on our business and / or require us to relinquish valuable rights. Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of equity offerings, debt financings, collaborations, strategic alliances, and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of current stockholders may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect the rights of our current stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, 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. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, scale back or discontinue the development and commercialization of one or more of our product candidates or delay our pursuit of potential in- licenses or acquisitions. Our largest shareholder may use its significant interest to take actions not supported by our other shareholders. As of March ~~24~~ **25**, ~~2023~~ **2024**, our largest shareholder, Dong- A beneficially owned ~~45~~ **57**. ~~7~~ **2** % of our voting rights **. As a result**, ~~and if the warrants held by~~ Dong- A **is** ~~were exercised, Dong- A would hold 60. 3 % of our voting rights. As a result, Dong- A may be~~ able to exert a significant influence on the outcome of corporate actions requiring shareholder approval, including mergers, share capital increases and other extraordinary items. In addition, pursuant to the Investor Rights Agreement between us and Dong- A, Dong- A has the right to appoint a number of our directors commensurate with its percentage holding of our common stock, which may result in Dong- A controlling both the determinations of the Board ~~of Directors~~ and the vote of all matters submitted to a vote of our shareholders, which enables them to control all corporate decisions. This concentration of ownership may delay, deter or prevent acts that would be favored by our other shareholders. The interests of Dong- A may not always coincide with our interests or the interests of our other shareholders. For as long as Dong- A owns shares of our common stock and the Investor Rights Agreement is effective, Dong- A will have significant influence on our management, business plans and policies, including the appointment and removal of **members of** our ~~officers~~ **board of directors (" Board ")**, decisions on whether to raise future capital and amending our ~~charter~~ **certificate of incorporation** and bylaws, which govern the rights attached to our common stock. In particular, **with** ~~if Dong- A owns~~ a significant **ownership** percentage of our stock, Dong- A will be able to cause or prevent a change of control of us or a change in the composition of our Board and could preclude any unsolicited acquisition of us. The concentration of ownership could deprive you of an opportunity to receive a premium for your shares of common stock as part of a sale of ~~us~~ **NeuroBo** and ultimately might affect the market price of our common stock. In addition, this concentration of ownership may adversely affect the trading price of our common stock because investors may perceive disadvantages in owning shares in a company with significant stockholders. Dong- A and its affiliates engage in a broad spectrum of activities, including investments in the healthcare industry generally. In the ordinary course of its business activities, Dong- A and its affiliates may engage in activities where their interests conflict with our interests or those of our other shareholders, such as investing in or advising businesses that directly or indirectly compete with certain portions of our business or are suppliers or customers of ours.

~~Our~~ **Nothing in our** certificate of incorporation provides that neither Dong- A or any of their affiliates or any director who is not employed by us (including any non- employee director who serves as one of our officers in both her or his director and officer capacities) or its affiliates have any duty to refrain from engaging, directly or indirectly, in the same business activities or similar business activities or lines of business in which we operate. Dong- A also may pursue acquisition opportunities that may be complementary to our business, and, as a result, those acquisition opportunities may not be available to us. In addition, Dong- A may have an interest in pursuing acquisitions, divestitures and other transactions that, in their judgment, could enhance its investment, even though such transactions might involve risks to ~~you~~ **our stockholders** . **We are** ~~64We may be~~ a ~~"~~ controlled company ~~"~~ within the meaning of the Nasdaq listing ~~rules~~ **requirements** and **as a result,** may ~~follow certain~~ **rely on** exemptions from certain corporate governance requirements ~~that could adversely affect our public shareholders. As of March 24, 2023, our largest shareholder, Dong- A beneficially owned 45. 7 % of our voting rights~~ . To the extent ~~that Dong- A acquires additional shares of common stock, including through the exercise of the warrants that it currently holds or otherwise, such that Dong- A would own more than 50 % of our outstanding common stock,~~ we ~~would meet the definition of a " controlled company " under the corporate governance standards for Nasdaq listed companies. For so long as we would be a " controlled company " under this definition, we would be eligible to utilize certain exemptions from the corporate governance requirements of Nasdaq, including the requirements (i) that a majority of the Board consist of independent directors, (ii) to have a governance committee that is composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities, (iii) to have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee' s purpose and responsibilities, (iv) that the compensation committee consider certain independence factors when engaging legal counsel and other committee advisors and (v) for an annual performance evaluation of the governance and compensation committees. Although we do not currently intend to~~ rely on **such** ~~the " controlled company "~~ exemptions ~~under the Nasdaq listing rules even if we would be deemed to a " controlled company~~ , **you will** ~~" we could elect to rely on these exemptions in the future. If we were to elect to rely on the " controlled company " exemptions, a majority of the members of the Board might not be independent directors and our nominating and corporate governance and compensation committees might not consist entirely of independent directors. Accordingly, if we rely on the exemptions, during the period we remain a controlled company and during any transition period following a time when we are no longer a controlled company, stockholders would~~ not have the same protections afforded to ~~shareholders~~ **stockholders** of companies that are subject to **such** ~~all of the~~ corporate governance requirements **. Because of the voting power over our Company held by Dong- A and the Investor Rights Agreement between such parties, we are considered a controlled company for the purposes of the Nasdaq listing requirements. As such, we are exempt from the corporate governance requirements that our Board, compensation committee, and nominating and corporate governance committee meet the standard of independence established by those corporate governance requirements. The independence standards are intended to ensure that directors who meet the independence standards are free of any conflicting interest that could influence their actions as directors. We do not currently utilize the exemptions afforded to a controlled company, though we are entitled to do so. To the extent we utilize these exemptions, you will not have the same protections afforded to stockholders of companies that are subject to all of the corporate governance requirements** of Nasdaq. Provisions in our corporate charter documents and under Delaware law ~~could~~ **may** make an acquisition of ~~us~~ **NeuroBo** , which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our certificate of incorporation and the bylaws may discourage, delay or prevent a merger, acquisition or other change in control of us that stockholders may consider favorable, including transactions in which our stockholders might otherwise receive a premium for their shares. These provisions could also limit the price that investors might be willing to pay in the future for shares of our common stock, thereby depressing the market price of our common stock. In addition, because our board is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by stockholders to replace or remove their current management by making it more difficult for stockholders to replace members of our board. Among other things, these provisions: ● establish a classified ~~board~~ **Board** ~~of directors~~ such that not all members of the board are elected at one time; ● allow the authorized number of our directors to be changed only by resolution of our ~~board~~ **Board** ~~of directors~~ ; ● limit the manner in which our stockholders can remove directors from the ~~board~~ **Board** ; ● establish advance notice requirements for stockholder proposals that can be acted on at stockholder meetings and nominations to our ~~board~~ **Board** ~~of directors~~ ; ● require that stockholder actions must be effected at a duly called stockholder meeting and prohibit actions by our stockholders by written consent; ● prohibit our stockholders from calling special meetings; ● authorize our board to issue preferred stock without stockholder approval, which preferred stock may include rights superior to the rights of the holders of common stock, and which could be used to institute a shareholder rights plan, or so- called" poison pill," that would work to dilute the stock ownership of a potential hostile acquirer, effectively preventing acquisitions that have not been approved by our board; and ● require the approval of the holders of at least two- thirds of the votes that all our stockholders would be entitled to cast to amend or repeal certain provisions of our charter or bylaws. Moreover, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which prohibits a person who owns in excess of 15 % of our outstanding voting stock from merging or combining with it for a period of three years after the date of the transaction in which the person acquired in excess of 15 % of our outstanding voting stock, unless the merger or combination is approved in a prescribed manner. ~~65We~~ **We may fail to comply with the continued listing requirements of the Nasdaq, such that our common stock may be delisted and the price of our common stock and our ability to access the capital markets could be negatively impacted. Our common stock is listed for trading on Nasdaq. We must satisfy Nasdaq' s continued listing requirements, including, among other things, a minimum closing bid price requirement of $ 1. 00 per share for thirty consecutive business days (the " Minimum Bid Price Requirement "). We have in the past been notified by Nasdaq that we were not in compliance with the Minimum Bid Price Requirement, and while**

we have regained compliance, there can be no assurance that we will remain compliant with the Minimum Bid Price Requirement, or any other Nasdaq continued listing requirements. A delisting of our common stock from Nasdaq could materially reduce the liquidity of our common stock and result in a corresponding material reduction in the price of our common stock. In addition, delisting could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in the potential loss of confidence by investors, employees and fewer business development opportunities. We are a" smaller reporting company" and we cannot be certain if the reduced reporting requirements applicable to such companies could make our common stock less attractive to investors. We are a" smaller reporting company", as defined in the Exchange Act. For as long as we continue to be an smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not" emerging growth companies", including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (Sarbanes- Oxley Act), only being required to provide two years of audited financial statements in **our** annual reports and reduced disclosure obligations regarding executive compensation in ~~its~~ **our** periodic reports and proxy statements. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile. We have identified material weaknesses in our internal control over financial reporting that could, if not remediated, result in material misstatements in our financial statements or impair our ability to produce accurate and timely consolidated financial statements. We concluded that there were material weaknesses relating to our internal control over financial reporting relating to a lack of segregation of duties over certain financial processes, management review over financial reporting and logical access to financial reporting systems. For more information about these material weaknesses, see Part II, Item 9A ~~(~~**.** Controls and Procedures ~~)~~of this report. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of **our** ~~the company' s~~ annual or interim consolidated financial statements will not be prevented or detected on a timely basis. Although we have begun to take measures to remediate these material weaknesses, the measures we have taken, and expect to take, to improve our internal controls may not be sufficient to address the issues identified, to ensure that our internal controls are effective or to ensure that the identified material weaknesses will not result in a material misstatement of our annual or interim consolidated financial statements. If we are unable to correct material weaknesses or deficiencies in internal controls in a timely manner, our ability to record, process, summarize and report financial information accurately and within the time periods specified in the rules and forms of the SEC will be adversely affected. This failure could negatively affect the market price and trading liquidity of our common stock, cause investors to lose confidence in our reported financial information, subject us to civil and criminal investigations and penalties, and materially and adversely impact our business and financial condition. General Risk ~~FactorsOur~~ --- **Factors Our** business and operations ~~would~~ **may** suffer in the event of system failures or unplanned events. Despite the implementation of security measures, our internal computer systems and those of our current and future contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we are not aware of any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed. Furthermore, any unplanned event, such as flood, fire, explosion, tornadoes, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize the facilities, may have an adverse effect on our ability to operate the business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. ~~66We~~ **We** rely significantly on information technology and any failure, inadequacy, interruption or security lapse of that technology or loss of data, including any cyber security incidents, ~~could~~ **may** compromise sensitive information related to our business, prevent us from accessing critical information or expose us to liability which could harm our ability to operate our business effectively and adversely affect our business and reputation. In the ordinary course of our business, our contract research organizations and other third parties on which we rely 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. These applications and data encompass a wide variety of business- critical information, including ~~research and development~~ **R & D** information and business and financial information. The secure processing, storage, maintenance and transmission of this critical information is vital to our operations and business strategy. Despite the implementation of security measures, our internal computer systems and those of third parties with which we contract are vulnerable to damage from cyber- attacks, computer viruses, breaches, unauthorized access, interruptions due to employee error or malfeasance or other disruptions, or damage from natural disasters, terrorism, war and telecommunication and electrical failures. Any such event could compromise our networks and the information stored there could be accessed by unauthorized parties, publicly disclosed, lost or stolen. We have measures in place that are designed to detect and respond to such security incidents and breaches of privacy and security mandates. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, government enforcement actions and regulatory penalties. Unauthorized access, loss or dissemination could also disrupt our operations, including our ability to conduct research, development and commercialization activities, process and prepare Company financial

information, manage various general and administrative aspects of our business and damage our reputation, in addition to possibly requiring substantial expenditures of resources to remedy, any of which could adversely affect our business. The loss of clinical trial data could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. In addition, there can be no assurance that we will promptly detect any such disruption or security breach, if at all. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and our research, development and commercialization efforts could be delayed. An active trading market for our common stock may not be maintained. Our common stock is currently traded on ~~the~~ Nasdaq ~~Capital Market~~ , but we can provide no assurance that we will be able to maintain an active trading market for our shares on ~~the~~ Nasdaq ~~Capital Market~~ or any other exchange in the future. If there is no active market for our common stock, it may be difficult for our stockholders to sell shares without depressing the market price for the shares or at all. If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our ~~stock~~ **business** , the price of our stock could decline. If one or more analysts cover our business and downgrade their evaluations of our stock or publish inaccurate or unfavorable research about our business, the price of our stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price and trading volume to decline. We incur increased costs as a result of operating as a public company and our management is required to devote substantial time to compliance initiatives. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the stock exchange upon which our common stock is listed **,** and other applicable securities rules and regulations impose various requirements on public companies, including establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our management and other personnel devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time- consuming and costly. However, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may ~~67evolve~~ -- **evolve** over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices. Stockholder activism, the current political environment and the current high level of government intervention and regulatory reform may lead to substantial new regulations and disclosure obligations, which may lead to additional compliance costs and impact the manner in which we operate our business in ways we cannot currently anticipate. We are a" smaller reporting company", as defined in the Exchange Act. For as long as we continue to be an smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not" emerging growth companies", including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act of 2002 (Sarbanes- Oxley Act), only being required to provide two years of audited financial statements in **our** annual reports and reduced disclosure obligations regarding executive compensation in ~~its~~ **our** periodic reports and proxy statements **.** If **(i) the market value of** our ~~public float~~ **voting and non- voting ordinary shares held by non- affiliates** is ~~above~~ **less than** $ ~~75~~ **250. 0** million ~~as of~~ **measured on** the last business day of our **second fiscal quarter or (ii) (a) our annual revenue is less than $ 100. 0 million during the** most recently completed **fiscal year and (b) the market value of our voting and non- voting ordinary shares held by non- affiliates is less than $ 700. 0 million measured on the last business day of our** second fiscal quarter ~~or~~ , if before such date, we opt to no longer take advantage of the applicable exemption, we will be required to include an opinion from our independent registered public accounting firm on the effectiveness of our internal control over financial reporting. To achieve compliance with Section 404, we are required to engage in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we must dedicate internal resources, hire additional finance and accounting personnel, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. During the course of our review and testing, we may identify deficiencies and be unable to remediate them before we must provide the required reports. We or our independent registered public accounting firm may not be able to conclude on an ongoing basis that we have effective internal control over financial reporting, which could harm our operating results, cause investors to lose confidence in our reported financial information and cause the trading price of our stock to fall. In addition, as a public company we are required to timely file accurate quarterly and annual reports with the SEC under the Exchange Act. In order to report ~~our~~ **the** results of **our** operations and financial ~~statements~~ **position** on an accurate and timely basis, we will depend on CROs to provide timely and accurate notice of their costs to ~~it~~ **us** . Any failure to report our financial results on an accurate and timely basis could result in sanctions, lawsuits, delisting of our shares from Nasdaq or other adverse consequences that would materially harm our business. We do not anticipate declaring or paying, in the foreseeable future, any cash dividends on our capital stock and, consequently, the ability of our stockholders to achieve a return on their investment will depend on appreciation in the price of our common stock. We have never declared or paid any cash dividend on our capital stock and do not currently intend to do so in the foreseeable future. We currently anticipate that we will retain future earnings for the development, operation and expansion of our business. Therefore, the success of an investment in shares of our common stock will depend upon any future appreciation in their value. There is no guarantee that shares of our common stock will appreciate in value or even maintain the price at which you purchased them. Our ~~Bylaws~~ **bylaws** designate the Court of Chancery of the State of Delaware as the sole and exclusive forum for certain types of actions and proceedings that may be initiated by our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees. Our ~~Bylaws~~ **bylaws** provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will generally be the

sole and exclusive forum for any derivative action or proceeding brought on ~~its~~ **our** behalf, any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers or other employees to us or our stockholders, any action asserting a claim arising pursuant to any provision of the Delaware General Corporation Law, as amended, the certificate of incorporation or the bylaws or any other action asserting a ~~68~~ **claim governed by the internal affairs doctrine. This provision does not apply to claims arising under the Securities Act and the Exchange Act or any claim for which the federal courts have exclusive jurisdiction. Any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock shall be deemed to have notice of and to have consented to the provisions of the bylaws described above. This choice of forum provision may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits against us and our directors, officers and employees. Alternatively, if a court were to find this provision inapplicable to, or unenforceable in respect of, one or more of the specified types of actions or proceedings, we may incur additional costs associated with resolving such matters in other jurisdictions, which could adversely affect our business and financial condition. Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and stock price. The global credit and financial markets have experienced extreme volatility and disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. We cannot assure you that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require it to delay or abandon clinical development plans. In addition, there is a risk that one or more of our current service 59**