Risk Factors Comparison 2025-03-04 to 2024-04-01 Form: 10-K

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Investing in our securities involves a high degree of risk. In addition to the risks related to our business set forth in this Annual Report on Form 10- K and the other information included and incorporated by reference in this Annual Report on Form 10- K, you should carefully consider the risks described below before purchasing our securities. Additional risks, uncertainties and other factors not presently known to us or that we currently deem immaterial may also impair our business operations. Risks Relating to Our Company We have incurred net losses every year and quarter since our inception and anticipate that we will continue to incur net losses in the future. We are a clinical stage biotechnology pharmaceutical company that is focused on the discovery and development of medications for the treatment of addictions and related disorders of AUD in patients with certain targeted genotypes. We have a limited operating history. Investment in biopharmaceutical product development is highly speculative because it entails substantial upfront capital expenditures and significant risk that any potential product candidate will fail to demonstrate adequate effect or an acceptable safety profile, gain regulatory approval and become commercially viable. We have no products approved for commercial sale and have not generated any revenue from product sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. To date, we have not generated positive cash flow from operations, revenues, or profitable operations, nor do we expect to in the foreseeable future. As of December 31, ~~2023~~ **2024** , we had an accumulated deficit of approximately $ ~~68~~ **82** . ~~8~~ **0** million. We expect our research and development expenses to increase when we commence our clinical development program in the US. Even if we succeed in commercializing our product candidate or any future product candidates, we expect that the commercialization of our product will not begin until 2025 or later, we will continue to incur substantial research and development and other expenditures to develop and market additional product candidates and will continue to incur substantial losses and negative operating cash flow. We may encounter unforeseen expenses, difficulties, complications, delays and other unknown factors that may adversely affect our business. The size of our future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenue. Our prior losses and expected future losses have had and will continue to have an adverse effect on our shareholders' equity and working capital. Our independent registered public accounting firm has expressed doubt about our ability to continue as a going concern. The report of our independent registered public accounting firm contains a note stating that the accompanying financial statements have been prepared assuming we will continue as a going concern. During the year ended December 31, ~~2023~~ **2024** , we incurred a net loss of approximately $ ~~5~~ **13** . ~~1~~ **2** million and used cash in operations of approximately $ 6. ~~8~~ **9** million. Losses have principally occurred as a result of the research and development efforts coupled with no operating revenue. Until we begin generating revenue, there is substantial doubt about our ability to continue as a going concern. We currently have no product revenues and may not generate revenue at any time in the near future, if at all. Currently, we have no products approved for commercial sale. We currently have no products for sale and we cannot guarantee that we will ever have any drug products approved for sale. We and our product candidate are subject to extensive regulation by the FDA, and comparable regulatory authorities in other countries governing, among other things, research, testing, clinical trials, manufacturing, labeling, promotion, marketing, adverse event reporting and recordkeeping of our product candidates. Until, and unless, we receive approval from the FDA or other regulatory authorities for our product candidates, we cannot commercialize product candidates and will not have product revenues. Even if we successfully develop products, achieve regulatory approval, and then commercialize our products, we may be unable to generate revenue for many years, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations. For the foreseeable future, we will have to fund all of our operations from equity and debt offerings, cash on hand and grants. In addition, changes may occur that would consume our available capital at a faster pace than expected, including changes in and progress of our development activities, acquisitions of additional candidates and changes in regulation. Moreover, preclinical and clinical testing may not start or be completed as we forecast and may not achieve the desired results. Therefore, we expect to seek additional sources of funding, such as additional financing, grant funding or partner or collaborator funding, which additional sources of funding may not be available on favorable terms, if at all. We have had limited operations to date and there can be no assurance that we will be able to execute on our business strategy. We are a clinical stage company, as such, have had limited operations to date and need to rely on paid consultants to help us achieve our clinical, regulatory and overall business goals. We have yet to demonstrate our ability to overcome the risks frequently encountered in our industry and are still subject to many of the risks common to such enterprises, including our ability to implement our business plan, market acceptance of our proposed business and lead product, under- capitalization, cash shortages, limitations with respect to personnel, financing and other resources, competition from better funded and experienced companies, and uncertainty of our ability to generate revenues. In fact, though individual team members have experience running clinical trials, as a company we have yet to prove that we can successfully run a clinical trial to the point of releasing data. There is no assurance that our activities will be successful or will result in any revenues or profit, and the likelihood of our success must be considered in light of the stage of our development. In addition, no assurance can be given that we will be able to consummate our business strategy and plans, or that financial, technological, market, or other limitations may force us to modify, alter, significantly delay, or significantly impede the implementation of such plans. We have insufficient results for investors to use to identify historical trends. Investors should consider our prospects in light of the risk, expenses and difficulties we will encounter as an early stage company. Our revenue and income potential is unproven and our business model is continually evolving. We are subject to the risks inherent to the operation of a new business enterprise, and cannot assure you that we will be able to successfully address these risks. We will need to secure additional

financing in order to support our operations and fund our current and future clinical trials. We can provide no assurances that any additional sources of financing will be available to us on favorable terms, if at all. Our forecast of the period of time through which our current financial resources will be adequate to support our operations and the costs to support our general and administrative, selling and marketing and research and development activities are forward- looking statements and involve risks and uncertainties. If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned product development activities or obtain approval of our product candidate from the FDA and other regulatory authorities. We do not have any committed sources of capital. Moreover, if our future trial activities are significantly delayed due to pandemics or unrest, our project cost and operating overhead costs may significantly increase. In such case, we would need to obtain additional funding, either through other grants or through potentially dilutive means. In any case, we will need to raise additional capital to complete our development program and to meet our long- term business objectives. Our cash and cash equivalents at the date of this Annual Report filing on Form 10- K are not expected to be sufficient to fund our operations for the next twelve months. Given current expectations, we will require additional financing as we continue to execute our business strategy. Though we have recently received total net proceeds of approximately $ ~~3~~ **7** . 8 million from ~~recent~~ **equity sales and** warrant ~~exercises~~ **exercise fees** , we have determined to use these additional funds to accelerate our development of AD04. Moreover, we will require additional funds in order to continue operations and for additional clinical trials of AD04, if needed, as well as any additional clinical trials or other development of any products we may acquire or license. Our liquidity may be negatively impacted as a result of a research and development cost increases in addition to general economic and industry factors. We anticipate that, to the extent that we require additional liquidity, it will be funded through the incurrence of other indebtedness, additional equity financings or a combination of these potential sources of liquidity. In addition, we may raise additional funds to finance future cash needs through grant funding and / or corporate collaboration and licensing arrangements **. There can be no assurance that the new administration will devote significant funds to grants or that any grant money will be available to us** . If we raise additional funds by issuing equity securities or convertible debt, our stockholders will experience dilution. Debt financing, if available, would result in increased fixed payment obligations and may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. We are in discussions with potential partners that could fund a Phase 3 clinical program and / or commercialization of AD04, assuming a successful regulatory outcome; however, there can be no assurance that we will be successful in attracting such a partner. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our products, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us. The covenants under future credit facilities may limit our ability to obtain additional debt financing. We cannot be certain that additional funding will be available on acceptable terms, or at all. Any failure to raise capital in the future could have a negative impact on our financial condition and our ability to pursue our business strategies. Additional financing, which is not in place at this time, may be from the sale of equity or convertible or other debt securities in a public or private offering, from a credit facility or strategic partnership coupled with an investment in us or a combination of both. Our ability to raise capital through the sale of equity may be limited by the various rules of the ~~Securities and Exchange Commission (the "~~ SEC ~~")~~ and The Nasdaq Capital Market (the " Nasdaq "), which place limits on the number of shares of stock that may be sold. Equity issuances would have a dilutive effect on our stockholders. We may be unable to raise sufficient additional financing on terms that are acceptable to us, if at all. Our failure to raise additional capital and in sufficient amounts may significantly impact our ability to expand our business. For further discussion of our liquidity requirements as they relate to our long- term plans, see the section entitled " Management' s Discussion and Analysis of Financial Condition and Results of Operations — Liquidity and Capital Resources. " We have identified material weaknesses in our internal controls, and we cannot provide assurances that these weaknesses will be effectively remediated or that additional material weaknesses will not occur in the future. As a public company, we are subject to the reporting requirements of the Exchange Act, and the Sarbanes- Oxley Act. We expect that the requirements of these rules and regulations will continue to increase our legal, accounting and financial compliance costs, make some activities more difficult, time consuming and costly, and place significant strain on our personnel, systems and resources. The Sarbanes- Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures, and internal controls over financial reporting. We do not yet have effective disclosure controls and procedures, or internal controls over all aspects of our financial reporting. We are continuing to develop and refine our internal controls over financial reporting. Our management is responsible for establishing and maintaining adequate internal control over our financial reporting, as defined in Rule 13a- 15 (f) under the Exchange Act. We will be required to expend time and resources to further improve our internal controls over financial reporting, including by expanding our staff. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future. We have identified material weaknesses in our internal control over financial reporting. 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 financial statements will not be prevented or detected on a timely basis. The material weaknesses identified to date include (i) lack of formal risk assessment under COSO framework (ii) policies and procedures which are not adequately documented, (iii) lack of proper approval processes, review processes and documentation for such reviews, (iv) insufficient GAAP experience regarding complex transactions and ineffective review processes over period end financial disclosure and reporting (v) deficiencies in the risk assessment, design and policies and procedures over information technology (" IT ") general controls, and (vi) insufficient segregation of duties. We will be required to expend time and resources to further improve our internal controls over financial reporting, including by expanding our staff. However, we cannot assure you that our internal control over financial reporting, as modified, will enable us to identify or avoid material weaknesses in the future. Our current controls and any new controls that we develop may become inadequate because of changes in conditions in our business, including increased complexity resulting from our

international expansion. Further, weaknesses in our disclosure controls or our internal control over financial reporting may be discovered in the future. Any failure to develop or maintain effective controls, or any difficulties encountered in their implementation or improvement, could harm our operating results or cause us to fail to meet our reporting obligations and may result in a restatement of our financial statements for prior periods. Any failure to implement and maintain effective internal control over financial reporting could also adversely affect the results of management reports and independent registered public accounting firm audits of our internal control over financial reporting that we will eventually be required to include in our periodic reports that will be filed with the SEC. Ineffective disclosure controls and procedures, and internal control over financial reporting could also cause investors to lose confidence in our reported financial and other information, which would likely have a negative effect on the market price of our common stock. Our independent registered public accounting firm has not been required to audit the effectiveness of our internal control over financial reporting since we were, until December 31, 2023, an " emerging growth company " as defined in the JOBS Act. Because we are no longer an emerging growth company, and if we meet other requirements, our independent registered public accounting firm may issue a report that is adverse in the event it is not satisfied with the level at which our internal control over financial reporting is documented, designed or operating. Any failure to maintain effective disclosure controls and internal control over financial reporting could have a material and adverse effect on our business and operating results, and cause a decline in the market price of our common stock. We rely on a license to use various technologies that are material to our business and if the agreement were to be terminated or if other rights that may be necessary or we deem advisable for commercializing our intended products cannot be obtained, it would halt our ability to market our products and technology, as well as have an immediate material adverse effect on our business, operating results and financial condition. Our prospects are significantly dependent upon the UVA LVG License. The UVA LVG License grants us exclusive, worldwide rights to certain existing patents and related intellectual property that covers AD04, currently our only product candidate. If we breach the terms of the UVA LVG License, including any failure to make minimum royalty payments required thereunder or failure to reach certain developmental milestones and completion of deadlines, including, submitting an NDA by ~~December~~ **March** 31, ~~2024~~ **2028** and commencing commercialization of an FDA approved product by ~~December~~ **March** 31, ~~2025~~ **2029** , or other factors, including but not limited to, the failure to comply with material terms of the Agreement, the licensor has the right to terminate the license. If we were to lose or otherwise be unable to maintain this license on acceptable terms, or find that it is necessary or appropriate to secure new licenses from other third parties, we would not be able to market our products and technology, which would likely require us to cease our current operations which would have an immediate material adverse effect on our business, operating results and financial condition. As a result of our ongoing business and clinical development planning for AD04, we are approaching UVA LVG to extend the milestones referenced in our license agreement with UVA. Our business is dependent upon the success of our lead product candidate, AD04, which requires significant additional clinical testing before we can seek regulatory approval and potentially launch commercial sales. Our business and future success depends upon our ability to obtain regulatory approval of and then successfully commercialize our lead investigational product candidate, AD04 and other product candidates. AD04 is in clinical stage development. To date, our main focus and the investment of a significant portion of our efforts and financial resources has been in the development of our lead investigational product candidate, AD04, for which we recently completed the ONWARD Phase 3 clinical trial with 302 patients in Scandinavia and Central and Eastern Europe, which targets the reduction of risk drinking (heavy drinking of alcohol) in subjects that possess selected genetics of the serotonin transporter and / or 5- HT3 receptor gene. We currently plan to conduct two additional Phase 3 clinical trials, as well as one or more supportive clinical studies. Even though we are pursuing a registration pathway based on specific FDA input and guidance and the EMA precedents and guidance, there are many uncertainties known and unknown that may affect the outcome of the trial. These include adequate patient enrollment, adequate supply of our product candidate, potential changes in the regulatory landscape, and the results of the trial being successful. AD04 currently, as well as any potential future product candidates, will require additional clinical and non- clinical development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenue from product sales. We expect AD04 will need at least two additional Phase 3 trials (including the ONWARD Phase 3 trial we recently completed in Scandinavia and Central and Eastern Europe) and one or more supportive clinical studies to gain approval in either the U. S. or outside the US for AUD and additional development activity, including, without limitation, clinical trials, in order to seek approval for the use of AD04 to treat any other indications (e. g., such as opioid use disorder, gambling addiction, smoking cessation, and other drug addictions). In addition, because AD04 is our most advanced product candidate and there is limited history information on long- term effects of our proposed dosage, there is always a chance of developmental delays or regulatory issues or other problems arising, with our development plans and depending on their magnitude, our business could be significantly harmed. In any case, the costs associated with completion of our two additional Phase 3 trials, commercialization of AD04, and the costs of developing AD04 for use in other indications are significant and will require obtaining funding, possibly through equity sales, before AD04 generates revenue. Our future success depends heavily on our ability to successfully manufacture, develop, obtain regulatory approval, and commercialize AD04, which may never occur. We currently generate no revenues from our product candidate, and we may never be able to develop or commercialize a marketable drug. The active ingredient of our product candidate, ondansetron, is currently available in generic form. Ondansetron, the active pharmaceutical ingredient (" API ") of AD04, was granted FDA approval as Zofran ® in January 1991 and is approved in many foreign markets. Ondansetron is commercially available in generic form, but not available: (i) at the formulation / dosage levels expected to be marketed by us, or (ii) with a requirement to use a diagnostic biomarker, as we expect to be the case with AD04. Although ondansetron has been approved to treat nausea and emesis it has not been approved to treat AUD and it has not been approved for daily long- term use as planned by us. Clinical testing to date of ondansetron at the higher doses used to treat nausea / emesis have not shown effectiveness in treating AUD or any other addictive disorder; however, if a third party

conducted a Phase 3 clinical program and showed success treating AUD at those doses, we could not prevent such third party from marketing ondansetron for AUD at those doses. Results from clinical studies suggest that high intravenous doses of ondansetron may affect the electrical activity of the heart. In a Drug Safety Communication dated June 29, 2012, the FDA stated that: " A 32 mg single intravenous dose of ondansetron (Zofran, ondansetron hydrochloride, and generics) may affect the electrical activity of the heart (QT interval prolongation), which could pre- dispose patients to develop an abnormal and potentially fatal heart rhythm known as Torsades de Pointes. " In addition: " No single intravenous dose should exceed 16 mg. " There are also several recent lawsuits claiming that Zofran ® used for the unapproved use of morning sickness causes birth defects. Although we do not believe that our dosage will cause such adverse event there can be no assurance that the negative side effects of the generic drug that have been found in higher dosages will not occur in our dosage or otherwise deter potential users of our product candidate and adversely impact sales of our product candidate. If we were to be required to have such a warning on our drug label, patients may be deterred from using our product candidates. In addition, we also face the risk, that doctors will prescribe off label, the generic form of ondansetron to treat AUD despite the different dosage of ondansetron in the generic form from that in AD04, the lack of demonstrated clinical efficacy against AUD at the currently available doses (i. e., the Zofran ® and approved generics), and the potential safety concerns if the currently available / higher doses are taken chronically as would be needed for AUD or other addictions. Physicians, or their patients, could divide the lowest dose existing oral tablet into more than ten parts to approximate the necessary AD04 dosage. Although we believe that any attempt by competitors to reformulate and market ondansetron at our intended dosage levels, while technically feasible, infringes on our intellectual property rights, and should, accordingly, be actionable, we cannot give assurances that we would be successful in defending our rights or that we will have access to sufficient funds necessary to successfully prosecute any such violations of, or infringements on, our intellectual property rights. Additionally, we cannot ensure investors that other companies will not discover and seek to commercialize low doses of ondansetron, not currently available, for other indications. Changes in general economic conditions, geopolitical conditions, domestic and foreign trade policies, monetary policies and other factors beyond our control may adversely impact our business and operating results. Our operations and performance depend on global, regional and U. S. economic and geopolitical conditions. General worldwide economic conditions have experienced significant instability in recent years including the recent global economic uncertainty and financial market conditions. The uncertain financial markets, disruptions in supply chains, mobility restraints, and changing priorities as well as volatile asset values could impact our business in the future. The COVID- 19 outbreak and government measures taken in response to the pandemic have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, have spiked, while demand for other goods and services, such as travel, have fallen. We expect the same will be true for any other pandemic. The future progression of the pandemic and its effects on our business and operations are uncertain. In addition, the outbreak of a pandemic could disrupt our operations due to absenteeism by infected or ill members of management or other employees, or absenteeism by members of management and other employees who elect not to come to work due to the illness affecting others in our office or laboratory facilities, or due to quarantines. Pandemics could also impact members of our Board of Directors resulting in absenteeism from meetings of the directors or committees of directors, and making it more difficult to convene the quorums of the full Board of Directors or its committees needed to conduct meetings for the management of our affairs. Further, due to increasing inflation, operating costs for many businesses including ours have increased and, in the future, could impact demand or pricing manufacturing of our drug candidates or services providers, foreign exchange rates or employee wages. Inflation rates, particularly in the United States, have increased recently to levels not seen in years, and increased inflation may result in increases in our operating costs (including our labor costs), reduced liquidity and limits on our ability to access credit or otherwise raise capital. In addition, the Federal Reserve has raised, and may again raise, interest rates in response to concerns about inflation, which coupled with reduced government spending and volatility in financial markets may have the effect of further increasing economic uncertainty and heightening these risks. Actual events involving reduced or limited liquidity, defaults, non- performance or other adverse developments that affect financial institutions or other companies in the financial services industry or the financial services industry generally, or concerns or rumors about any events of these kinds, have in the past and may in the future lead to market- wide liquidity problems. For example, on March 10, 2023, Silicon Valley Bank, was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation as receiver. Although we did not have any cash or cash equivalent balances on deposit with Silicon Valley Bank, uncertainty and liquidity concerns in the broader financial services industry remain and the failure of Silicon Valley Bank and its potential near- and long- term effects on the biotechnology industry and its participants such as our vendors, suppliers, and investors, may also adversely affect our operations and stock price. We are actively monitoring the effects these disruptions and increasing inflation could have on our operations. These conditions make it extremely difficult for us to accurately forecast and plan future business activities. While there exists a large body of evidence supporting the safety of our primary API, ondansetron, under short- term use, there are currently no long- term use clinical safety data available. We intend to market our products, particularly AD04, for long- term use by patients seeking to reduce their number of days of heavy drinking, and we assume future sales volumes reflecting such extended use. Studies of Zofran ® conducted as part of its FDA and other regulatory agencies review process found that the drug is well- tolerated and results in few adverse side effects at dosages almost 100 times the dosage expected to be formulated in AD04. However, to the best of our knowledge, no comprehensive clinical study has been performed to date that has evaluated the safety profile of ondansetron for long- term use. We expect the FDA will require us to provide safety data in at least 100 patients for 12 months and can offer no assurances that safety results of these long term use studies will lead to any subsequent approval for long- term use. There can be no assurance that long- term usage of ondansetron, at dosages anticipated by us, will be safe. Though the FDA has stated it will not require additional non- clinical testing nor will it require a QT interval

prolongation clinical study, such statements by the FDA are not legally binding on the agency. The current data for our lead product candidate, AD04 are the result of Phase 2 clinical trials conducted by third parties as well as data generated from the ONWARD trial we conducted and do not currently provide sufficient evidence that our products are viable as potential pharmaceutical products. Through our proprietary access to relevant laboratory and clinical trial results of the University of Virginia' s research program, and through our reliance on publicly available third- party research, we possess toxicology, pharmacokinetic, and other preclinical data and clinical data on AD04. As of now, AD04 has completed only Phase 2 clinical trials and **one** ~~we are now completing our first~~ Phase 3 trial. There is no guarantee that Phase 2 results can or will be replicated by **additional** pivotal Phase 3 studies. To date, long- term safety and efficacy have not yet been demonstrated in clinical trials for our investigational product candidate. Favorable results in early studies or trials may not be repeated in later studies or trials. Even if our clinical trials are initiated and completed as planned, we cannot be certain that the results will support our product candidate claims. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful. We cannot be sure that the results of later clinical trials would replicate the results of prior clinical trials and preclinical testing, nor that they would satisfy the requirements of the FDA or other regulatory agencies. Clinical trials may fail to demonstrate that our product candidate is safe for humans and effective for indicated uses. Preclinical and clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals or commercialization. Any delay in, or termination of, our clinical trials would delay our obtaining FDA or other global regulatory approval for the affected product candidate and, ultimately, our ability to commercialize that product candidate. On July 20, 2022, we announced the results from the ONWARD ™ Phase 3 trial. Although the trial missed the primary endpoint, it did show statistical significance in a pre- defined patient group. AD04 patients, compared with placebo patients, achieved a statistically significant reduction from baseline at month six in percentage of heavy drinking days (PHDD) for the pre- specified patient group of heavy drinkers. across all genotypes combined (avg. < 10 drinks per drinking day at baseline; p = 0. 03), which accounted for approximately two- thirds of the trial population. A similar trend was seen in the combined month five and six analysis in the reduction from baseline (p = 0. 07). Notably, in the last month of the trial, AD04 heavy drinking patients had a mean reduction of approximately 79 % in heavy drinking compared with baseline. Compared with placebo patients, AD04 patients in the heavy drinking group had an overall significant difference in the severity of their AUD diagnosis (p = 0. 04) under the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM- 5). For the group of those who no longer meet AUD criteria (< 2 symptoms), the comparisons were 27. 4 % vs. 14. 9 % (i. e., an 84 % decrease), of AD04 and placebo patients, respectively. These data underscore the clinical relevance of the findings that heavy drinking AUD patients that receive AD04 appear more likely to recover from the disease by the end of the treatment regimen. Additionally, and consistent with the Phase 2b trial, AD04 had a safety and tolerability profile that was similar to placebo. No side effects or severe adverse events (SAEs) were determined to be related to AD04 treatment. In fact, more SAEs were reported in the placebo group compared with the AD04 group (7 on placebo vs. 3 on AD04). There were two cardiac events in placebo group and none in the AD04 group. Comparing overall Adverse Events (AEs), the profiles between AD04 and placebo were similar. AEs reported with a frequency of 5 % or more of patients in either group were: headache (11 % on placebo, 12 % on AD04), insomnia (3 % on placebo, 7 % on AD04), blood magnesium decreased (5 % on placebo, 6 % on AD04), and fatigue (3 % on placebo, 6 % on AD04). All of the AE' s were reported as mild to moderate. Importantly, in the overall category of cardiac disorders, patients on placebo showed a greater number of adverse events compared to AD04 (7 % on placebo, 4 % on AD04), in addition to greater number of cardiac SAEs in the placebo group as reported above. As a result of the above clinical trials, Adial will have to conduct additional clinical trials to meet US and global regulatory requirements for approval. The FDA and / or other global regulators may not accept our planned Phase 3 endpoints for final approval of AD04 and may determine additional clinical trials are required for approval of AD04. The FDA has indicated to us that a comparison of the percent of patients with no heavy drinking days in the last two months of a six month clinical trial between the drug and placebo groups will be a satisfactory endpoint for determination of a successful Phase 3 trial of AD04 and has published the draft guidance Alcoholism: Developing Drugs for Treatment Guidance for Industry dated February 2015 indicating this endpoint for the development of drugs for AUD. Similarly, the EMA has in the past accepted the co- primary endpoints of reduction from baseline in days of heavy drinking and reduction total grams of alcohol consumed per month and has published the Guideline on the development of medicinal products for the treatment of alcohol dependence on February 18, 2010 stating these endpoints as approvable endpoints for alcohol addiction treatment. Despite these indications, neither the FDA nor the EMA is bound to accept the stated endpoint if a new drug application for AD04 is submitted and their definitions of a heavy drinking day may change. We, however, can offer no assurance that the FDA or EMA will approve our primary endpoints, that we can achieve success at the any endpoints they do approve, or that these potential benefits will subsequently be realized. We will incur additional costs and our approvals could be delayed if the FDA or other global regulators requires additional clinical trials in patients that are negative for the genotypes targeted by AD04. In addition, clinical trials conducted with only genotype positive subjects will likely result in labeling restricted to treating patients that are genotype positive. Although the FDA has indicated that it sees little evidence of positive effects for the use of AD04 in subjects that are negative for the genotypes targeted by AD04 and has stated that it would not object to the AD04 Phase 3 clinical trials going forward without including these additional subjects, the FDA has indicated that some research in this area may be required prior to approval of AD04 for AUD within the marker negative population. We believe data in genotype negative patients will be needed to satisfy FDA requirements, and necessary for approval of the genetic test with CDRH. We intend to conduct two additional Phase 3 trials that will not include the additional subjects and therefore we expect the label for AD04 to be restricted. If the results of such studies are not positive for AD04, it may result in AD04 not being approved. Under the Pediatric Research Equity Act (" PREA "), NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. We plan to test AD04 in adolescent patients (ages 12- 17) as part of our

next Phase 3 trial. If successful, we intend to request labeling for treating adolescent patients. Under PREA, an applicant may request and be granted a waiver based on meeting specific criteria as outlined in guidance published in February 2023. Our use of the currently manufactured clinical trial material in the planned Phase 3 trial is dependent upon the review and approval of the relevant regulatory agencies and authorities. The Company has manufactured additional clinical trial material for use in the other studies that may be required by the FDA or EMA. No assurance can be given that the CMC plan developed by us will be satisfactory to the regulatory agencies or that the clinical trial material produced for use in clinical trials of AD04 will be approved for use in the trials, either of which could result in delay of the clinical trial program and a requirement for increased investment prior to commencement of clinical trials. Our investigational product, AD04, is dependent on a successful development, approval, and commercialization of a genetic test, which is expected to be classified as a companion diagnostic. Treatment with AD04 will be dependent on identification of patients with a genetic test (i. e., a companion diagnostic). Companion diagnostics and complementary diagnostics are regulated as medical devices by the FDA and, as such, require either clearance or approval prior to commercialization. While the technology for the test we plan to use is well established, it cannot be certain the testing laboratory we set up will be able to conduct the test with the selectivity and sensitivity that will be required or that the genetic test will be approved by FDA for such use, which could increase the time and cost to develop AD04 and possibly prevent marketing approval. While we have been party to a joint meeting with the Center for Drug Evaluation and Research (" CDER ", the FDA division responsible for drug approvals) and the ~~Center for Devices and Radiological Health (" CDRH "~~, the FDA division responsible for device approvals, including genetic tests) at which agreement was reached as to the development path for the genetic test, neither CDER nor CDRH is bound to accept our planned submission package even if the data is positive. We expect to need approval of a PMA or a 510 (k) from CDRH for the companion diagnostics to be used with the drug product. We have collected and are storing additional blood samples from all patients enrolled in the ONWARD Phase 3 trial, and plan to do so for any future trials that may be conducted, in the event of any difficulties, however, we cannot be certain we can overcome all of the technological, logistical or regulatory hurdles related to the genetic testing, which include, without limitation, technical validation of the test (e. g. specificity, sensitivity, reproducibility, robustness of methods), clinical validation acceptable to CDER and CDRH, all of which are needed for approval of AD04 and its companion diagnostic genetic test. Failure in any of these areas could delay approval of AD04, increase the cost necessary to achieve approval of AD04 or prevent approval of AD04. If we obtain approval of AD04 and its genetic test, we currently plan to distribute the genetic test through an approved third party clinical testing lab partner in order to achieve wider availability of the genetic test to drive market uptake of AD04. However, we cannot be sure that third party testing companies will be willing to provide the test, that reimbursement for the test will be available to make such business profitable, or that taking a genetic test will be acceptable to patients or physicians. Our product candidate will require extensive clinical and other testing. Our product candidate will require extensive clinical and other testing. Although our product candidate has completed a 283- patient Phase ~~2b~~ **2** clinical trial and has **also** completed ~~its first~~ **an initial 302- patient** Phase 3 clinical trial, we anticipate completing two additional Phase 3 clinical trials in order to obtain regulatory approval and therefore cannot predict with any certainty if or when we might submit an application for regulatory approval for any of our product candidates or whether any such application will be accepted for review by the FDA or other global regulators, or whether any application will be approved upon review. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our proposed indications. Success in preclinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing. Results from earlier clinical trials may not be repeated in later clinical trials. The clinical trial process may fail to demonstrate that our product candidate is safe and effective for their proposed uses. This failure could cause us to abandon our product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay and possibly preclude the filing of any NDAs with the FDA or other global regulators and, ultimately, our ability to commercialize our product candidate and generate product revenues. Our clinical trials may fail to demonstrate adequately the safety and efficacy of AD04 or any future product candidates, which would likely prevent or delay regulatory approval and commercialization. Before obtaining regulatory approvals for the commercial sale of AD04 or any future product candidates, including AD04, we must demonstrate through lengthy, complex and expensive preclinical testing and clinical trials that product candidates are both safe and effective for use in each target indication. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical trial process. The results of preclinical studies and early and even later stage clinical trials of product candidates may not be predictive of the results of later- stage clinical trials. Results from subsequent clinical trials may not be the same as the results from the Phase 2b clinical trial that was conducted by the University of Virginia or the results of our Phase 3 trial. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. We can make no assurances that, should our future Phase 3 studies provide statistically significant and clinical meaningful results evidencing that treatment with AD04 results in reduced days of heavy drinking or abstinence, these same results will also provide evidence of greater patient efficacy rates and or patient benefit ratios vis- à- vis currently marketed drug treatments. Most product candidates that commence clinical trials are never approved as products. In addition, even if the trials are successfully completed, we cannot guarantee that the FDA or foreign regulatory authorities will interpret the results as we do, and more trials could be required before we submit product candidates for approval. To the extent that the results of the trials are not satisfactory to the FDA or foreign regulatory authorities for support of a marketing application, approval of product candidates may be significantly delayed, or we may be required to expend significant additional resources, which may not be available to us, to conduct

additional trials in support of potential approval of product candidates. If we experience delays in the enrollment of patients in our clinical trials our receipt of necessary regulatory approvals could be delayed or prevented. We plan to conduct two additional Phase 3 clinical trials in order to obtain regulatory approval and therefore our inability to locate and continue to enroll a sufficient number of eligible patients in any future clinical trials would result in significant delays or may require us to abandon one or more clinical trials. Retention of subjects in clinical trials related to AUD can be challenging relative to trials in some other indications due to the nature of the target population. Our ability to enroll patients in trials is affected by many factors out of our control including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the trial, the design of the clinical trial, the prevalence and successful recruiting of patients that are genotype positive, 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. Due to the use of a biomarker to determine enrollment in our current and planned Phase 3 clinical trials, we will have a limited population of patients to draw from for our Phase 3 clinical trials. Our success will be dependent upon adoption by physicians and others. Even if the FDA and / or EMA approves our product candidate or any future product candidates we may develop or acquire, the product will require acceptance among physicians, healthcare payers, patients, and the medical community. Our product is to be used in combination with a genetic test targeted at patients with certain specified genotypes. It is anticipated that physicians will recommend patients for screening prior to administration of AD04 or future product candidates. Therefore, our business will be substantially dependent upon our ability to communicate with and obtain support from physicians regarding the benefits of our products relative to alternative treatments available at that time. Rapid technological change and substantial competition may impair the business. The pharmaceutical industry is subject to rapid and substantial technological change. Technological competition in the industry from pharmaceutical and biotechnology companies, universities, governmental entities, and others diversifying into the field is intense and is expected to increase. Many of these entities have significantly greater research and development capabilities, as well as substantially more marketing, financial, and managerial resources than we do, and represent significant competition. Acquisitions of, or investments in, competing biotechnology companies by large pharmaceutical companies could increase these competitors' financial, marketing, and other resources. We cannot assure you that developments by others will not render our products or technologies noncompetitive or that we will be able to keep pace with technological developments. Competitors have developed, or are in the process of developing, technologies that are, or in the future may be, the basis for competitive products. Some of these products may have an entirely different approach or means of accomplishing similar therapeutic endpoints than products we are currently developing. These competing products may be more effective and less costly than the products that we are developing. In addition, conventional behavioral therapies and other treatment approaches currently in use today may continue to be used instead of, rather than in conjunction with, our products. Any product that we successfully develop, and for which we gain regulatory approval, must compete for market acceptance and market share. Accordingly, important competitive factors, in addition to completion of clinical testing and the receipt of regulatory approval, will include product efficacy, safety, timing, and scope of regulatory approvals, availability of supply, marketing and sales capability, reimbursement coverage, pricing, and patent protection. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer. We will compete against fully integrated pharmaceutical companies such as Alkermes and Indivior and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have drugs already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs or have substantially greater financial resources than we do, as well as significantly greater experience in: ● developing drugs, and other therapies; ● undertaking preclinical testing and clinical trials; ● obtaining FDA and other regulatory approvals of drugs, biologics and other therapies; ● formulating and manufacturing drugs, biologics and other therapies; and ● launching, marketing and selling drugs, and other therapies. Risks Relating to Our Business and Industry If we do not obtain the necessary regulatory approvals in the United States and / or other countries, we will not be able to sell our product candidates. We cannot assure you that we will receive the approvals necessary to commercialize AD04 or any future product candidates we acquire or develop in the future. We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA- equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any product candidate, we must submit to the FDA an NDA, demonstrating that the product candidate is safe, pure and potent, and effective for its intended use. This demonstration requires significant research including preclinical studies, as well as clinical trials. We plan to conduct two additional Phase 3 clinical trials of AD04 for the treatment of AUD. Satisfaction of the FDA' s regulatory requirements typically takes many years, depends upon the type, complexity and novelty of the product candidate and requires substantial resources for research, development and testing. We cannot predict whether our clinical trials will demonstrate the safety and efficacy of our product candidates or if the results of any clinical trials will be sufficient to advance to the next phase of development or for approval from the FDA. We also cannot predict whether our research and clinical approaches will result in drugs or therapeutics that the FDA considers safe and effective for the proposed indications. The FDA has substantial discretion in the approval process. The approval process may be delayed by changes in government regulation, future legislation or administrative action, or changes in FDA policy that occur prior to or during our regulatory review. Factors that might lead to a suspension or termination of a clinical trial include, but are not limited to: ● failure to conduct the clinical trial in accordance with U. S., international and or local regulatory requirements; ● failure of medical investigators to follow clinical trial protocols; ● unforeseen safety issues; and / or ● lack of adequate funding to continue any clinical trial. Further, delays in obtaining regulatory approvals may: ● prevent or delay

commercialization of, and our ability to derive product revenues from, product candidates; and ● diminish any competitive advantages that we may otherwise believe that we hold. Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our applications. We may never obtain regulatory clearance for any product candidates. Failure to obtain FDA approval of any of product candidates will severely undermine our business by leaving us without a saleable product, and therefore without any source of revenues, until another product candidate can be developed. There is no guarantee that we will ever be able to develop or acquire another product candidate. In addition, the FDA may require us to conduct additional preclinical and clinical testing or to perform post- marketing studies, as a condition to granting marketing approval of a product. Initial acceptance by the FDA of clinical trial protocols is subject to constant review and any process control failures could result in additional required testing. Regulatory approval of products often requires that subjects in clinical trials be followed for long periods to assess their overall survival. The results generated after approval could result in loss of marketing approval, changes in product labeling, and / or new or increased concerns about the side effects or efficacy of a product. The FDA has significant post- market authority, including the explicit authority to require post- market studies and clinical trials, labeling changes based on new safety information, and compliance with FDA- approved risk evaluation and mitigation strategies. The FDA' s exercise of its authority has in some cases resulted, and in the future could result, in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post- approval regulatory requirements and potential restrictions on sales of approved products based on labeling or other requirements. In foreign jurisdictions, we must also receive approval from the appropriate regulatory authorities, and pricing authorities, before we can commercialize any candidate products. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. There can be no assurance that we will receive the approvals necessary to commercialize our product candidate for sale outside the United States. Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols or our development plan to reflect these changes. Amendments may require resubmitting clinical trial protocols to FDA and institutional review boards for reexamination, which may impact the costs, timing or successful completion of a clinical trial. If we experience delays in completion of, or if we terminate any clinical trials, the commercial prospects for product candidates may be harmed, and the ability to generate product revenues will be delayed. 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 product candidates. Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not mean that we will be successful in obtaining regulatory approval of product candidates in other jurisdictions. Obtaining and maintaining regulatory approval of product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, and a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, comparable regulatory authorities in foreign jurisdictions must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials, as clinical studies conducted in one jurisdiction may not be accepted by or sufficient for regulatory authorities in other jurisdictions. In many jurisdictions outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that jurisdiction. In some cases, the price that we intend to charge for our candidate products is also subject to approval. Additionally, some foreign jurisdictions require participation of subjects from their country in the Phase 3 trials in order to gain approval in their country. We intend to also submit marketing applications in other jurisdictions, including European countries. Regulatory authorities in jurisdictions outside of the United States have requirements for approval of product candidates with which we must comply prior to marketing in those jurisdictions. Obtaining foreign regulatory approvals and compliance with foreign regulatory requirements could result in significant delays, difficulties and costs for us and could delay or prevent the introduction of our products in certain countries. If we fail to comply with the regulatory requirements in international markets and / or fail to receive applicable marketing approvals, our target market will be reduced and our ability to realize the full market potential of AD04 or any future product candidates will be harmed. Even if we receive regulatory approval of AD04 or any future product candidates, we will be subject to ongoing regulatory obligations, such as post market surveillance and current good manufacturing practice (" GMP ") requirements, and continued regulatory review, which may result in significant additional expense. We may also be subject to penalties if we fail to comply with regulatory requirements or experience unanticipated problems with product candidates. In addition, third parties on whom we rely must comply with regulatory requirements, and any non- compliance on their part may negatively impact our business, assuming we obtain regulatory authorization at all. Any regulatory approvals that we receive for product candidates will require surveillance to monitor the safety and efficacy of the product candidate. The FDA may also require a Risk Evaluation and Mitigation Strategy (" REMS ") program in order to approve product candidates, which could entail requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. The FDA could also require a boxed warning, sometimes referred to as a Black Box Warning on the product label to identify a particular safety risk, which could affect commercial efforts to promote and sell the product. In addition, if the FDA or a comparable foreign regulatory authority approves product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for product candidates will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post- marketing information and reports, registration, as well as continued compliance with current GMPs and current good clinical practices (" GCPs ") for any clinical trials that we conduct post- approval. We are also subject to certain user fees imposed by the regulatory agencies. Later discovery of previously unknown problems with product candidates, including adverse events of unanticipated severity or frequency, or with our third- party manufacturers or manufacturing

processes, or failure to comply with regulatory requirements, may result in, among other things: ● restrictions on the marketing or manufacturing of product candidates, withdrawal of the product from the market, or product recalls; ● fines, warning letters or holds on clinical trials; ● refusal by the FDA to approve pending applications or supplements to approved applications filed by us or suspension or revocation of approvals; ● product seizure or detention, or refusal to permit the import or export of product candidates; and ● injunctions or the imposition of civil or criminal penalties. The FDA' s and other regulatory authorities' policies may change, such as those required by the 21st Century Cures Act, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of AD04 or any future product candidates. In addition, it is unclear what changes, if any, the new presidential administration may bring. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained and we may not achieve or sustain profitability. Clinical trials are very expensive, time- consuming and difficult to design and implement. As part of the regulatory process, we must conduct clinical trials for each product candidate to demonstrate safety and efficacy to the satisfaction of the FDA and other regulatory authorities. As we advance AD04 or any future product candidates we expect that our expenses will increase when we commence the two planned Phase 3 clinical trials of AD04 for the treatment of AUD. The number and design of the clinical trials that will be required varies depending upon product candidate, the condition being evaluated, current medical strategies and the trial results themselves. Therefore, it is difficult to accurately estimate the cost of the clinical trials. Clinical trials are very expensive and difficult to design and implement, in part because they are subject to rigorous regulatory requirements. The clinical trial process is also time consuming. We estimate that clinical trials of product candidates including AD04, will take at least several years to complete. Furthermore, failure can occur at any stage of the trials, and we could encounter problems that cause us to abandon or repeat clinical trials. The commencement and completion of clinical trials may be delayed or prevented by several factors, including: ● unforeseen safety issues; ● failure to determine appropriate dosing; ● greater than anticipated cost of our clinical trials; ● failure to demonstrate effectiveness during clinical trials; ● slower than expected rates of subject recruitment or difficulty obtaining investigators; ● subject drop- out or discontinuation; ● inability to monitor subjects adequately during or after treatment; ● third party contractors, including, without limitation, CRO' s and manufacturers, failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner; ● reaching agreements with prospective CROs, and trial sites, both of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; ● insufficient or inadequate supply or quality of product candidates or other necessary materials to conduct our trials; ● potential additional safety monitoring, or other conditions required by FDA or comparable foreign regulatory authorities regarding the scope or design of our clinical trials, or other studies requested by regulatory agencies; ● problems engaging Institutional Review Boards (" IRBs "), to oversee trials or in obtaining and maintaining IRB approval of studies; ● imposition of clinical hold or suspension of our clinical trials by regulatory authorities; and ● inability or unwillingness of medical investigators to follow our clinical protocols. In addition, we or the FDA may suspend or terminate our clinical trials at any time if it appears that we are exposing participants to unacceptable health risks or if the FDA finds deficiencies in our Investigational New Drug, or IND, submissions or the conduct of these trials. Therefore, we cannot predict with any certainty when, if ever, future clinical trials will commence or be completed. AD04 and any future product candidates may cause undesirable side effects or have other properties that could halt their clinical development, prevent their regulatory approval, limit their commercial potential or result in significant negative consequences. Undesirable side effects caused by AD04 or any future product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approval by the FDA or other comparable foreign regulatory authorities. Results of our trials could reveal a high and unacceptable severity and prevalence of side effects or other unexpected characteristics. If unacceptable safety concerns or other adverse events arise in the development of a product candidate, our clinical trials could be suspended or terminated or the FDA or comparable foreign regulatory authorities could order us to cease clinical trials or deny approval of such product candidate for any or all targeted indications. Treatment- related side effects could also affect patient recruitment or the ability of enrolled subjects to complete the trial or result in potential product liability claims. Inadequate training in recognizing or managing the potential side effects of a product candidate could result in patient deaths. Any of these occurrences may harm our business, financial condition and prospects significantly. We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits. The testing and marketing of drug product candidates entail an inherent risk of product liability. Product liability claims might be brought against us by consumers, health care providers or others selling or otherwise coming into contact with our products. Clinical trial liability claims may be filed against us for damages suffered by clinical trial subjects or their families. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products which could impact our ability to continue as a going concern. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with collaborators. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● decreased demand for any approved product candidates; ● impairment of our business reputation; ● withdrawal of clinical trial participants; ● costs of related litigation; ● distraction of management' s attention; ● substantial monetary awards to patients or other claimants; ● loss of revenues; and ● the inability to successfully commercialize any approved drug candidates. There is uncertainty as to market acceptance of our technology and product candidates. Even if the FDA approves our current product candidate, or any future product candidates we may develop or acquire, the products may not gain broad market acceptance among physicians, healthcare payers, patients, and the medical community. We have conducted our own research into the markets for our product candidates; however, we cannot guarantee market acceptance of

our product candidates, if approved, and have somewhat limited information on which to estimate our anticipated level of sales. Product candidates, if approved, will require payers, healthcare providers and doctors to adopt our technology. Our industry is susceptible to rapid technological developments and there can be no assurance that we will be able to match any new technological advances. If we are unable to match the technological changes in the needs of our customers, the demand for our products will be reduced. Acceptance and use of any products we market, assuming market authorization approval at all, will depend upon a number of factors including: ● perceptions by members of the health care community, including physicians, about the safety and effectiveness of our products; ● limitation on use or warnings required by FDA in our product labeling; ● cost- effectiveness of our products relative to competing products; ● convenience and ease of administration; ● potential advantages of alternative treatment methods; ● availability of reimbursement for our products from government or other healthcare payers; and ● effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any. Because we expect virtually all of our product revenues for the foreseeable future to be generated from sales of AD04, if approved, the failure of this product to find market acceptance would substantially harm our business and would adversely affect our revenue. Even if we are able to obtain regulatory approval for our product candidate or any product candidates we develop or acquire, we will continue to be subject to ongoing and extensive regulatory requirements, and our failure, or the failure of our contract manufacturers, to comply with these requirements could substantially harm our business. If the FDA approves our product candidate or any product candidates we develop or acquire, the labeling, manufacturing, packaging, adverse events reporting, storage, advertising, promotion and record- keeping for our products will be subject to ongoing FDA requirements and continued regulatory oversight and review. We may also be subject to additional FDA post- marketing obligations. If we are not able to maintain regulatory compliance, we may not be permitted to market product candidates and / or may be subject to product recalls or seizures. The subsequent discovery of previously unknown problems with any marketed product, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the product, and could include withdrawal of the product from the market. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements. We are exposed to the risk of employee fraud or other illegal activity by our employees, independent contractors, consultants, commercial partners and vendors. Misconduct by these parties could include intentional, reckless and / or negligent conduct that fails to: (i) comply with the laws of the FDA and other similar foreign regulatory bodies; (ii) provide true, complete and accurate information to the FDA and other similar foreign regulatory bodies; (iii) comply with manufacturing standards we have established; (iv) comply with healthcare fraud and abuse laws in the United States and similar foreign fraudulent misconduct laws; or (v) report financial information or data accurately or to disclose unauthorized activities to us. Any such misconduct or noncompliance could negatively affect the FDA' s review of our regulatory submission, including delaying approval or disallowance of certain information to support the submission, and / or delay a federal or state healthcare program' s or a commercial insurer' s determination regarding the availability of future reimbursement for product candidates. If we obtain FDA approval of any product candidates and begin commercializing those products in the United States, our potential exposure under such laws will increase significantly, and our costs associated with compliance with such laws are also likely to increase. These laws may impact, among other things, our current activities with principal investigators and research patients, as well as proposed and future sales, marketing and education programs. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed 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, structuring and commission (s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The laws that may affect our ability to operate or may require us to modify certain programs include, but are not limited to: ● the federal Anti- Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs; ● federal civil and criminal false claims laws and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment or approval from Medicare, Medicaid, or other third- party payors (both governmental and private) that are false or fraudulent or knowingly making a false statement to improperly avoid, decrease or conceal an obligation to pay money to a federal or state healthcare program or private payor; ● the federal Health Insurance Portability and Accountability Act of 1996 (" HIPAA "), which, among other things, created new federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e. g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters; ● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (" HITECH "), and their respective implementing regulations, which, among other things, impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of such individually identifiable health information; ● the federal Physician Payment Sunshine Act, created under the Healthcare Reform Act (as defined herein), and its implementing regulations, which require certain manufacturers of drugs, devices, biologicals and medical supplies for which payment is available under Medicare, Medicaid or

the Children' s Health Insurance Program (with certain exceptions) to report annually to the United States Department of Health and Human Services (" HHS "), information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; ● federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and ● the Foreign Corrupt Practices Act (the " FCPA ") and similar antibribery and anticorruption laws in other countries that, for example, prevent improper payments or transfers of anything of value to foreign officials for the purpose of gaining commercial advantage, obtaining or retaining business, or to enhancing clinical trials. Additionally, we are subject to state and foreign equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. It is not always possible to identify and deter employee misconduct, and the precautions we take to detect and prevent inappropriate conduct may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the approval and commercialization of any product candidates outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws. We have no experience selling, marketing or distributing products and have no internal capability to do so. We currently have no sales, marketing or distribution capabilities, including, without limitation, capabilities to market AD04 or its companion genetic test. We do not anticipate having the resources in the foreseeable future to allocate to the sales and marketing of our proposed products, if approved. Our future success depends, in part, on our ability to enter into and maintain collaborative relationships for such capabilities, the collaborator' s strategic interest in the products under development and such collaborator' s ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that our collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources and time will be required to establish and develop an in- house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third party collaborators or develop in- house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties over whom we have no control, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to successfully market and sell our products in the United States or overseas on our own. We may not be successful in establishing and maintaining strategic partnerships, which could adversely affect our ability to develop and commercialize products. We may seek to enter into strategic partnerships in the future, including alliances with other biotechnology or pharmaceutical companies, to enhance and accelerate the development and commercialization of our products, such as a third party drug development company. We face significant competition in seeking appropriate strategic partners and the negotiation process is time- consuming and complex and can be costly. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for any future product candidates and programs because our research and development pipeline may be insufficient, our product candidates and programs may be deemed to be at too early of a stage of development for collaborative effort and / or third parties may not view our product candidates and programs as having the requisite potential to demonstrate safety and efficacy or return on investment. Even if we are successful in our efforts to establish strategic partnerships, the terms that we agree upon may not be favorable to us and we may not be able to maintain such strategic partnerships if, for example, development or approval of a product candidate is delayed or sales of an approved product are disappointing. If we ultimately determine that entering into strategic partnerships is in our best interest but either fail to enter into, are delayed in entering into or fail to maintain such strategic partnerships: ● the development of our current product candidate or certain future product candidates may be terminated or delayed; ● our planned clinical trials may be restructured or terminated; ● our cash expenditures related to development of our current product candidate or certain future product candidates may increase significantly and we may need to seek additional financing; ● we may be required to hire additional employees or otherwise develop expertise, such as sales and marketing expertise, for which we have not budgeted; ● we will bear all of the risk related to the development of any such product candidates; and ● the competitiveness of any product candidate that is commercialized could be reduced. To the extent we elect to enter into licensing or collaboration agreements to partner AD04 or any future product candidates, our dependence on such relationships may adversely affect our business. Our commercialization strategy for certain product candidates may depend on our ability to enter into agreements with collaborators to obtain assistance and funding for the development and potential commercialization of these investigational product candidates. Supporting diligence activities conducted by potential collaborators and negotiating the financial and other terms of a collaboration agreement are long and complex processes with uncertain results. Even if we are successful in entering into one or more collaboration agreements, collaborations may involve greater uncertainty for us, as we have less control over certain aspects of our collaborative programs than we do over our proprietary development and commercialization programs. Our

collaborators could delay or terminate their agreements, and our product candidates subject to collaborative arrangements may never be successfully developed or commercialized. Further, our future collaborators may develop alternative products or pursue alternative technologies either on their own or in collaboration with others, including our competitors, and the priorities or focus of our collaborators may shift such that our programs receive less attention or fewer resources than we would like, or they may be terminated altogether. Any such actions by our collaborators may adversely affect our business prospects and ability to earn revenues. In addition, we could have disputes with our future collaborators, such as the interpretation of terms in our agreements. Any such disagreements could lead to delays in the development or commercialization of any potential products or could result in time- consuming and expensive litigation or arbitration, which may not be resolved in our favor. We may face particular data protection, data security and privacy risks in connection with the European Union' s Global Data Protection Regulation and other privacy regulations. Outside of the United States, the laws, regulations and standards in many jurisdictions apply broadly to the collection, use, and other processing of personal information. For example, in the European Union, the collection and use of personal data are governed by the provisions of the General Data Protection Regulation (the " GDPR "). The GDPR, together with national legislation, regulations and guidelines of the European Union. member states governing the processing of personal data, impose strict obligations on entities subject to the GDPR, including but not limited to: (i) accountability and transparency requirements, and enhanced requirements for obtaining valid consent from data subjects; (ii) obligations to consider data protection as any new products or services are developed and to limit the amount of personal data processed; (iii) obligations to comply with the data protection rights of data subjects; and (iv) obligations to report certain personal data breaches to governmental authorities and individuals. Data protection authorities from the different E. U. member states and other European countries may enforce the GDPR and national data protection laws differently, and introduce additional national regulations and guidelines, which adds to the complexity of processing European personal data. Failure to comply with the requirements of the GDPR and the related national data protection laws may result in significant monetary fines and other administrative penalties (the GDPR authorizes fines for certain violations of up to 4 % of global annual revenue or € 20 million, whichever is greater) as well as civil liability claims from individuals whose personal data was processed. Additionally, expenses associated with compliance could reduce our operating margins. The GDPR also prohibits the transfer of personal data from the E. U. to countries outside of the E. U. unless made to a country deemed by the European Commission to provide adequate protection for personal data or accomplished by means of an approved data transfer mechanism (e. g., standard contractual clauses). Data protection authority guidance and enforcement actions that restrict companies' ability to transfer data may increase risk relating to data transfers or make it more difficult or impossible to transfer E. U. personal data to the U. S. Any failure to maintain the security of information relating to our patients, customers, employees and suppliers, whether as a result of cybersecurity attacks or otherwise, could expose us to litigation, government enforcement actions and costly response measures, and could disrupt our operations and harm our reputation. Significant disruptions to our information technology systems or breaches of information security could adversely affect our business. In connection with the pre- clinical and clinical development, sales and marketing of our products and services, we may from time to time transmit confidential information. We also have access to, collect or maintain private or confidential information regarding our clinical trials and the patients enrolled therein, employees, and suppliers, as well as our business. Although we have instituted security measures, there can be no assurance that these security measures will be able to protect against cyberattacks. Cyberattacks are rapidly evolving and becoming increasingly sophisticated. It is possible that computer hackers and others might compromise our security measures, or security measures of those parties that we do business with now or in the future, and obtain the personal information of patients in our clinical trials, vendors, employees and suppliers or our business information. A security breach of any kind, including physical or electronic break- ins, computer viruses and attacks by hackers, employees or others, could expose us to risks of data loss, litigation, government enforcement actions, regulatory penalties and costly response measures, and could seriously disrupt our operations. Any resulting negative publicity could significantly harm our reputation, which could cause us to lose market share and have an adverse effect on our results of operations. We rely extensively on our information technology systems, and our systems and infrastructure face certain risks, including cybersecurity and data leakage risks. We rely on our information technology systems and infrastructure to process transactions, summarize results and manage our business, including maintaining client and supplier information. In the ordinary course of business, we collect, store and transmit large amounts of confidential information, and it is critical that we do so in a secure manner to maintain the confidentiality and integrity of such confidential information. Additionally, we utilize third parties, including cloud providers, to store, transfer and process data. Our information technology systems, as well as the systems of our suppliers and other partners, whose systems we do not control, are vulnerable to outages and an increasing risk of continually evolving deliberate intrusions to gain access to company sensitive information. The size and complexity of our information technology systems, and those of our third- party vendors with whom we contract, make such systems potentially vulnerable to service interruptions and security breaches from inadvertent or intentional actions by our employees, partners or vendors, from attacks by malicious third parties, or from intentional or accidental physical damage to our systems infrastructure maintained by us or by third parties. Data security incidents and breaches by employees and others with or without permitted access to our systems pose a risk that sensitive data may be exposed to unauthorized persons or to the public. Maintaining the secrecy of this confidential, proprietary, or trade secret information is important to our competitive business position. While we have taken steps to protect such information and invested in information technology, there can be no assurance that our efforts will prevent service interruptions or security breaches in our systems or the unauthorized or inadvertent wrongful use or disclosure of confidential information that could adversely affect our business operations or result in the loss, dissemination, or misuse of critical or sensitive information. A cyber- attack or other significant disruption involving our information technology systems, or those of our vendors, suppliers and other partners, could also result in disruptions in critical systems, corruption or loss of data and theft of data, funds or intellectual property. A breach of our security measures or the accidental loss, inadvertent disclosure, unapproved dissemination, misappropriation or misuse of trade secrets, proprietary

information, or other confidential information, whether as a result of theft, hacking, fraud, trickery or other forms of deception, or for any other reason, could enable others to produce competing products, use our proprietary technology or information, or adversely affect our business or financial condition. We may be unable to prevent outages or security breaches in our systems. We remain potentially vulnerable to additional known or yet unknown threats as, in some instances, we, our suppliers and our other partners may be unaware of an incident or its magnitude and effects. We also face the risk that we expose our vendors or partners to cybersecurity attacks. Any or all of the foregoing could adversely affect our results of operations and our business reputation. Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches. Despite the implementation of security measures, our internal computer systems and those of our future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure 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 our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. Since we rely on third parties for research and development of AD04 and expect do so for future product candidates and for the manufacture of product candidates and to conduct clinical trials, similar events relating to their computer systems could also have a material adverse effect on our business. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of product candidates could be delayed. We have limited protection for our intellectual property. Our licensed patents and proprietary rights may not prevent us from infringing on the rights of others or prohibit potential competitors from commercializing products. We intend to rely on a combination of common law copyright, patent, trademark, and trade secret laws and measures to protect our proprietary information. We have licensed patents to protect certain of our proprietary intellectual property and have obtained exclusive rights to license certain of the technology for which patent protection has been obtained; however, such protection does not prevent unauthorized use of such technology. Trademark and copyright protections may be limited, and enforcement could be too costly to be effective. It may also be possible for unauthorized third parties to copy aspects of, or otherwise obtain and use, our proprietary information without authorization, including, but not limited to, product design, software, customer and prospective customer lists, trade secrets, copyrights, patents and other proprietary rights and materials. Other parties can use and register confusingly similar business, product and service names, as well as domain names, which could divert customers, resulting in a material adverse effect on our business, operating results and financial condition. We have not conducted an exhaustive patent search and cannot assure you that patents do not exist or could not be filed that would negatively affect our ability to market our products or maintain our competitive position with respect to our products. Additionally, our licensed patents may not prevent others from developing competitive products using related technology. Furthermore, other companies that obtain patents claiming products or processes useful to us may bring infringement actions against us. As a result, we may be required to obtain licenses from others to develop, manufacture or market our products. We cannot assure you that we will be able to obtain any such licenses on commercially reasonable terms, if at all. We also rely on trade secrets and proprietary know- how that we seek to protect, in part, by confidentiality agreements with our employees, consultants, suppliers, and licensees. We cannot give any assurance that these third parties will not breach these agreements, that we would have adequate remedies for any breach, or that our trade secrets will not otherwise become known or be independently developed by competitors. We cannot assure you that the U. S. Patent and Trademark Office (“ USPTO ”) will approve pending patent applications for intellectual property for which we are currently the exclusive worldwide licensee, or that any patent issued to, or licensed by, us will provide protection that has commercial significance. In this regard, the patent position of pharmaceutical compounds and compositions is particularly uncertain. Even issued patents may later be modified or revoked by the USPTO in proceedings instituted by others or by us. In addition, we cannot assure you that our licensed patents will afford protection against competitors with similar compounds or technologies, that others will not obtain patents with claims similar to those covered by our licensed patents or applications, or that the patents of others will not adversely affect our ability to conduct our business. Despite licensing patents issued in more than 40 jurisdictions around the world, continuing to achieve additional foreign patent issuances and maintaining and defending foreign patents may be more difficult than defending domestic patents because of differences in patent laws, and our licensed patent position therefore may be stronger in the United States than abroad. In addition, the protection provided by foreign patents, once they are obtained, may be weaker than that provided in the United States. If we fail to successfully enforce our intellectual property rights, our competitive position could suffer, which could harm our operating results. Competitors may challenge the validity or scope of our licensed patents or future patents we may obtain or license. In addition, our licensed patents may not provide us with a meaningful competitive advantage. We may be required to spend significant resources to monitor and police our licensed intellectual property rights. We may not be able to detect infringement and our competitive position may be harmed. In addition, competitors may design around our technology or develop competing technologies. Intellectual property rights may also be unavailable or limited in some foreign countries, which could make it easier for competitors to capture market share. The technology we license, our products or our development efforts may be found to infringe upon third- party intellectual property rights. Our commercial success depends in part on us avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in other jurisdictions. Recently, under the American Invents Act (“ AIA ”), new procedures including inter parties review and post grant review have been implemented. These procedures are relatively new and the manner in which they are being implemented continues to evolve, which brings additional uncertainty to our licensed patents and pending applications. Numerous U. S. and foreign issued patents

and pending patent applications, which are owned by third parties, exist in the fields in which we are developing product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may give rise to claims of infringement of the patent rights of others. Third parties may, in the future, assert claims or initiate litigation related to their patent, copyright, trademark and other intellectual property rights in technology that is important to us. The asserted claims and / or litigation could include claims against us, our licensors or our suppliers alleging infringement of intellectual property rights with respect to our products or components of those products. Regardless of the merit of the claims, they could be time consuming, result in costly litigation and diversion of technical and management personnel, or require us to develop a non- infringing technology or enter into license agreements. We have not undertaken an exhaustive search to discover any third party intellectual patent rights which might be infringed by commercialization of the product candidates described herein. Although we are not currently aware of any such third party intellectual patent rights, it is possible that such rights currently exist or might be obtained in the future. In the event that a third party controls such rights and we are unable to obtain a license to such rights on commercially reasonable terms, we may not be able to sell or continue to develop our products, and may be liable for damages for such infringement. We cannot assure you that licenses will be available on acceptable terms, if at all. Furthermore, because of the potential for significant damage awards, which are not necessarily predictable, it is not unusual to find even arguably unmeritorious claims resulting in large settlements. If any infringement or other intellectual property claim made against us by any third party is successful, or if we fail to develop non- infringing technology or license the proprietary rights on commercially reasonable terms and conditions, our business, operating results and financial condition could be materially adversely affected. If our products, methods, processes and other technologies infringe the proprietary rights of other parties, we could incur substantial costs and we may have to: ● obtain licenses, which may not be available on commercially reasonable terms, if at all; ● abandon an infringing drug or therapy candidate; ● redesign our products or processes to avoid infringement; ● stop using the subject matter claimed in the patents held by others; ● pay damages; or ● defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources. Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. We cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of product candidates. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize product candidates, which could harm our business significantly. We may be involved in lawsuits to protect or enforce the patents of our licensors, which could be expensive, time- consuming and unsuccessful. Competitors may infringe the patents of our licensors. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that one or more of our licensed patents 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 licensed patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our licensed patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our licensed patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure. Interference proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to some of our licensed patents or patent applications subject to pre- AIA or those of our licensors. An unfavorable outcome could result in a loss of our current licensed patent rights and could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent, alone or with our licensors, misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the United States. A derivation proceeding is a trial proceeding conducted at the Patent Trial and Appeal Board to determine whether (i) an inventor named in an earlier application derived the claimed invention from an inventor named in the petitioner' s application; and (ii) the earlier application claiming such invention was filed without authorization. An applicant subject to the first- inventor- to- file provisions may file a petition to institute a derivation proceeding only within one year of the first publication of a claim to an invention that is the same or substantially the same as the earlier application' s claim to the invention. The petition must be supported by substantial evidence that the claimed invention was derived from an inventor named in the petitioner' s application. Derivation proceedings may result in a decision adverse to our interests and, even if we are successful, may result in substantial costs and distract our management and other employees. 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. If securities analysts or investors perceive these results to be negative, it could have a

substantial adverse effect on the price of our shares of common stock. Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. 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, documentary, fee payment and other similar provisions 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 non- compliance 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. Noncompliance 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. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business. Patents are subject to changing legal interpretation by the USPTO and the Courts. If the U. S. Supreme Court, other federal courts, or the USPTO were to change the standards of patentability such changes could have a negative impact on our business. Recent court cases have made it more difficult to protect certain types of inventions. For instance, on October 30, 2008, the Court of Appeals for the Federal Circuit issued a decision that methods or processes cannot be patented unless they are tied to a machine or involve a physical transformation. On March 20, 2012, in the case Mayo v. Prometheus, the U. S. Supreme Court invalidated a patent focused on a diagnostic process because the patent claim embodied a law of nature. On July 3, 2012, the USPTO issued its Interim Guidelines for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature in view of the Prometheus decision. It remains to be seen how these guidelines will play out in the actual prosecution of diagnostic claims. Similarly, it remains to be seen how lower courts will interpret the Prometheus decision. Some aspects of our technology involve processes that may be subject to this evolving standard and we cannot guarantee that any of our pending process claims will be patentable as a result of such evolving standards. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. Our ability to generate product revenues will be diminished if our products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement. Our ability to commercialize our products, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from: ● government and health administration authorities; ● private health maintenance organizations and health insurers; and ● other healthcare payers. Patients generally expect that products such as ours are covered and reimbursed by third- party payors for all or part of the costs and fees associated with their use. If such products are not covered and reimbursed then patients may be responsible for the entire cost of the product, which can be substantial. Therefore, health care providers generally do not prescribe products that are not covered and reimbursed by third- party payors in order to avoid subjecting their patients to such financial liability. The existence of adequate coverage and reimbursement for the products by government and private insurance plans is central to the acceptance of AD04 and any future products we provide. During the past several years, third- party payors have undertaken cost- containment initiatives including different payment methods, monitoring health care expenditures, and anti- fraud initiatives. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for AD04 or any of our other products or may make no payment at all. Furthermore, the health care industry in the United States has experienced a trend toward cost containment as government and private insurers seek to control health care costs by imposing lower payment rates and negotiating reduced contract rates with service providers. Therefore, we cannot be certain that our services will be reimbursed at a level that is sufficient to meet our costs. Obtaining coverage and reimbursement approval of a product from a government or other third- party payor is a time- consuming and costly process that could require us to provide to the payor supporting scientific, clinical and cost- effectiveness data for the use of our products. Even if we obtain coverage for a given product, the resulting reimbursement payment rates might not be adequate for us to achieve or sustain profitability or may require co- payments that patients find unacceptably high. Patients are unlikely to use AD04 or any future product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of AD04 or any future product candidates. We intend to seek approval to market AD04 and future product candidates in both the United States and in selected foreign jurisdictions. If we obtain approval in one or more foreign jurisdictions for AD04 or any future product candidates, we will be subject to rules and regulations in those jurisdictions. In some foreign countries, particularly those in the European Union, the pricing of drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval of a product candidate. In addition, market acceptance and sales of product candidates will depend significantly on the availability of adequate coverage and reimbursement from third- party payors for product candidates and may be affected by existing and future health care reform measures. Third- party payors, whether domestic or foreign, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In both the United States and certain foreign jurisdictions, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our products profitably. In particular, in 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the " Healthcare Reform Act "), was enacted. The Healthcare Reform Act and its implementing regulations, among other things, revised the methodology by which rebates owed by manufacturers to the state

and federal government for covered outpatient drugs, including product candidates, under the Medicaid Drug Rebate Program are calculated, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program, extended the Medicaid Drug Rebate program to utilization of prescriptions of individuals enrolled in Medicaid managed care organizations, subjected manufacturers to new annual fees and taxes for certain branded prescription drugs, and provided incentives to programs that increase the federal government' s comparative effectiveness research. Other legislative changes have been proposed and adopted in the United States since the Healthcare Reform Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $ 1. 2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation' s automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2 % per fiscal year. In January 2013, President Obama signed into law the American Taxpayer Relief Act of 2012 (the " ATRA ") which delayed for another two months the budget cuts mandated by these sequestration provisions of the Budget Control Act of 2011. In March 2013, the President signed an executive order implementing sequestration, and in April 2013, the 2 % Medicare payment reductions went into effect. The ATRA also, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. There have been, and likely will continue to be, legislative and regulatory proposals at the foreign, federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future, particularly in light of the new presidential administration in the United States, and any proposed changes to healthcare laws that could potentially affect our clinical development or regulatory strategy. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and / or impose price controls may adversely affect: ● the demand for AD04, or future product candidates, if we obtain regulatory approval; ● our ability to set a price that we believe is fair for our products; ● our ability to generate revenue and achieve or maintain profitability; ● the level of taxes that we are required to pay; and ● the availability of capital. Any reduction in reimbursement from Medicare, Medicaid or other government programs may result in a similar reduction in payments from private payors, which may adversely affect our future profitability. If we are unable to obtain adequate coverage and reimbursement for our tests, it is unlikely that our tests will gain widespread acceptance. Use of our product candidate will require pre- treatment screening. Our strategy for AD04 aims to integrate pre- treatment screening into the drug label, effectively creating a patient- specific or " precision " treatment into one integrated therapeutic offering. Our ability to generate revenue will depend upon the availability of adequate coverage and reimbursement for our tests from third- party payors, including government programs such as Medicare and Medicaid, private insurance plans and managed care programs. Health care providers that order diagnostic services generally expect that those diagnostic services are covered and reimbursed by third- party payors for all or part of the costs and fees associated with the diagnostic tests they order. If such diagnostic tests are not covered and reimbursed then their patients may be responsible for the entire cost of the test, which can be substantial. Therefore, health care providers generally do not order tests that are not covered and reimbursed by third- party payors in order to avoid subjecting their patients to such financial liability. The existence of adequate coverage and reimbursement for the procedures performed by us by government and private insurance plans is central to the acceptance of our product candidate. During the past several years, third- party payors have undertaken cost-containment initiatives including different payment methods, monitoring health care expenditures, and anti- fraud initiatives. In addition, the Centers for Medicare & Medicaid Services, or CMS, which administers the Medicare program, has taken the position that the algorithm portion of multi- analyst algorithmic assays, or MAAAs, is not a clinical laboratory test and is therefore not reimbursable under the Medicare program. Although this position is only applicable to tests with a CMS determined national payment amount, it is possible that the local MACs, who make coverage and payment determinations for tests such as ours may adopt this policy and reduce payment for such test. If that were to happen, reimbursement for our pre-screening tests would be uncertain. We may not be able to achieve or maintain profitability if third- party payors deny coverage or reduce their current levels of payment, or if our costs of production increase faster than increases in reimbursement levels. Further, many private payors use coverage decisions and payment amounts determined by CMS as guidelines in setting their coverage and reimbursement policies. Future action by CMS or other government agencies may diminish payments to clinical laboratories, physicians, outpatient centers and / or hospitals. Those private payors that do not follow the Medicare guidelines may adopt different coverage and reimbursement policies for us and coverage and the amount of reimbursement under those polices is uncertain. For some governmental programs, such as Medicaid, coverage and reimbursement differ from state to state, and some state Medicaid programs may not pay an adequate amount for MyPRS ® or may make no payment at all. As the portion of the U. S. population over the age of 65 and eligible for Medicare continues to grow, we may be more vulnerable to coverage and reimbursement limitations imposed by CMS. Furthermore, the health care industry in the United States has experienced a general trend toward cost containment as government and private insurers seek to control health care costs through various mechanisms, including imposing limitations on payment rates and negotiating reduced contract rates with service providers, among other things. Therefore, we cannot be certain that our services will be reimbursed at a level that is sufficient to meet our costs. A variety of risks associated with marketing AD04 or any future product candidates internationally could materially adversely affect our business. We plan to seek regulatory approval of AD04 and any future product candidates outside of the United States, in particular in European markets, and, accordingly, we expect that we will be subject to additional risks related to operating in foreign countries if we obtain the necessary approvals, including: ● differing regulatory and reimbursement requirements in foreign countries; ● unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling

abroad; ● foreign taxes, including withholding of payroll taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; ● compliance with U. S. and foreign export control regulations, including economic sanctions and embargo programs, each of which may be subject to unexpected changes; ● difficulties staffing and managing foreign operations; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● potential liability under the FCPA or comparable foreign regulations; ● challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States; ● production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; ● business interruptions resulting from geo-political actions, including war and terrorism; and ● potential difficulties that may arise with pharmaceutical company partners under license or other agreement to jointly develop, seek regulatory approval, and commercialize our products. These and other risks associated with our international operations may materially adversely affect our ability to attain or maintain profitable operations. We may not successfully effect our intended expansion. Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we must expand our facilities, augment our operational, financial and management systems and hire additional qualified personnel. As our clinical, regulatory, and business planning is finalized, we may need to hire additional qualified personnel with expertise in preclinical and clinical research, government regulation, formulation and manufacturing, sales and marketing and accounting and financing. We compete for qualified individuals with numerous biopharmaceutical companies, universities and other research institutions. Competition for such individuals is intense, and we cannot be certain that our search for such personnel will be successful. Attracting and retaining qualified personnel will be critical to our success. If we are unable to manage our growth effectively, our business would be harmed. We rely on key executive officers and scientific, regulatory and medical advisors, and their knowledge of our business and technical expertise would be difficult to replace. Because of the specialized nature of our business, our ability to maintain a competitive position depends on our ability to attract and retain qualified management and other personnel. We cannot assure you that we will be able to continue to attract or retain such persons. We are highly dependent on our principal scientific, regulatory and medical advisors and our chief executive officer. We do not have an insurance policy on the life of our chief executive officer, Cary J. Claiborne; and we do not have " key person " life insurance policies for any of our other officers or advisors. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results. ~~Certain of our officers may have a conflict of interest. Certain of our officers are currently working for our company on a part- time basis and we expect that they will continue to do so. Our employment agreement with our Chief Financial Officer provides that he will devote 75 % of their business time, respectively, to our matters, with their remaining business time devoted to other matters including, without limitation, employment at other companies that are non-competitive with us, which may result in a lack of availability when needed due to responsibilities with other requirements. Our consulting agreement with our Chief Medical Officer provides that he will devote 75 % of his business time to our matters, with his remaining business time devoted to other matters including, without limitation, employment at other companies that are non-competitive with us, which may result in a lack of availability when needed due to responsibilities with other requirements.~~ Declining general economic or business conditions **and changes to trade policy, including tariff and customs regulations,** may have a negative impact on our business. Continuing concerns over U. S. health care reform legislation and energy costs, geopolitical issues, including those in Eastern Europe, the availability and cost of credit and government stimulus programs in the United States and other countries have contributed to increased volatility and diminished expectations for the global economy. These factors, combined with low business and consumer confidence and high unemployment, precipitated an economic slowdown and recession and stagnant economy for more than a decade. Additionally, political changes in the U. S. and elsewhere in the world have created a level of uncertainty in the markets. If the economic climate does not improve or deteriorate, our business, as well as the financial condition of our suppliers and our third- party payors, could be adversely affected, resulting in a negative impact on our business, financial condition and results of operations. **Changes in U. S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U. S. or other countries' trade policies may result in restrictions and economic disincentives on international trade. The U. S. government has recently imposed, or is currently considering imposing, tariffs on certain trade partners. Tariffs, economic sanctions and other changes in U. S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U. S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer- driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). Such changes have the potential to adversely impact the U. S. economy or certain sectors thereof, the global economy, and our industry, and as a result, could have a material adverse effect on our business, financial condition and results of operations.** In addition, the global macroeconomic environment could be negatively affected by, among other things, COVID-19 or other pandemics or epidemics, instability in global economic markets ~~, increased U. S. trade tariffs and trade disputes with other countries~~ , instability in the global credit markets, supply chain weaknesses, instability in the geopolitical environment as a result of the withdrawal of the United Kingdom from the European Union, the Russian invasion of Ukraine, the war in the Middle East and other political tensions, and foreign governmental debt concerns. Such challenges have caused, and may

continue to cause, uncertainty and instability in local economies and in global financial markets. Health care policy changes, including legislation reforming the U. S. health care system and other legislative initiatives, may have a material adverse effect on our financial condition, results of operations and cash flows. Government payors, such as Medicare and Medicaid, have taken steps and can be expected to continue to take steps to control the cost, utilization and delivery of health care services, including clinical laboratory test services. In March 2010, U. S. President Barack Obama signed the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, or collectively, the ACA, which made a number of substantial changes in the way health care is financed by both governmental and private insurers. It is unclear what, if any, changes the new administration will make to the health care system. We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. Risks Related to Our Securities and Investing in Our Securities Future sales and issuances of our common stock or rights to purchase common stock, including pursuant to our equity incentive plans and outstanding warrants, could result in additional dilution of the percentage ownership of our stockholders and could cause our stock price to fall. We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company. To raise capital, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell common stock, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing stockholders, and new investors could gain rights, preferences and privileges senior to the holders of our common stock. Pursuant to our 2017 equity incentive plan, which became effective on the business day prior to the public trading date of our common stock, our management is authorized to grant equity awards to our employees, officers, directors and consultants. Initially, the aggregate number of shares of our common stock that might be issued pursuant to stock awards under our 2017 equity incentive plan was 70, 000 shares, which has been since increased to ~~500~~ **2, 000**, 000 at our ~~2023~~ **2024** Annual Stockholders Meeting, and of which ~~212~~ **1**, ~~565~~ **098, 165** remain available for grant as of the date hereof. Increases in the number of shares available for future grant or purchase may result in additional dilution, which could cause our stock price to decline. At December 31, ~~2023~~ **2024**, we had outstanding (i) warrants to purchase 4, ~~390~~ **201**, ~~008~~ **568** shares of common stock outstanding at exercise prices ranging from $ 0. ~~001~~ **13** to $ 190. 86 (with a weighted average exercise price of $ ~~7~~ **8**. ~~47~~ **45**), and (ii) options to purchase ~~152~~ **733**, ~~194~~ **971** shares of common stock at a weighted average exercise price of $ ~~48~~ **9**. ~~00~~ **76** per share. The issuance of the shares of common stock underlying the options and warrants will have a dilutive effect on the percentage ownership held by holders of our common stock. At the date of this filing, we had outstanding (i) warrants to purchase 4, ~~132~~ **201**, 568 shares of common stock outstanding at exercise prices ranging from $ 0. 13 to $ 190. 86 (with a weighted average exercise price of $ 8. ~~54~~ **45**), and (ii) options to purchase ~~357~~ **763**, ~~194~~ **971** shares of common stock at a weighted average exercise price of $ ~~21~~ **9**. ~~23~~ **40** per share. The issuance of the shares of common stock underlying the options and warrants will have a dilutive effect on the percentage ownership held by holders of our common stock. We have additional securities available for issuance, which, if issued, could adversely affect the rights of the holders of our common stock. Our Certificate of Incorporation authorizes the issuance of 50, 000, 000 shares of common stock and 5, 000, 000 shares of preferred stock. The common stock and preferred stock, as well as the awards available for issuance under our 2017 equity incentive plan, can be issued by our board of directors, without stockholder approval. Any future issuances of such stock would further dilute the percentage ownership in us held by holders of our common stock and may be issued at prices below the initial price offering. In addition, the issuance of preferred stock may be used as an " anti- takeover " device without further action on the part of our stockholders, and may adversely affect the holders of the common stock. If we issue preferred stock with superior rights than our common stock, it could result in a decrease in the value of our common stock and delay or prevent a change in control of us. Our board of directors is authorized to issue 5, 000, 000 shares of preferred stock in series. The issuance of any preferred stock having rights superior to those of the common stock may result in a decrease in the value or market price of our common stock. Holders of preferred stock may have the right to receive dividends, certain preferences in liquidation and conversion rights and rights to elect directors. The issuance of preferred stock could, under certain circumstances, have the effect of delaying, deferring or preventing a change in control of us without further vote or action by the stockholders and may adversely affect the voting and other rights of the holders of our common stock. We have never paid dividends and have no plans to pay dividends in the future. Holders of our common stock are entitled to receive such dividends as may be declared by our board of directors. To date, we have paid no cash dividends on our preferred or common stock and we do not expect to pay cash dividends in the foreseeable future. We intend to retain future earnings, if any, to provide funds for operations of our business. Therefore, any return investors in our preferred or common stock may have will be in the form of appreciation, if any, in the market value of their common stock. Our failure to meet the continued listing requirements of The Nasdaq Capital Market could result in a de- listing of our common stock. Our shares of common stock are listed for trading on The Nasdaq Capital Market (" Nasdaq ~~'~~ **"**) under the symbol " ADIL. " If we fail to satisfy the continued listing requirements of The Nasdaq Capital Market such as the corporate governance requirements, the stockholder' s equity requirement or the minimum closing bid price requirement, The Nasdaq Capital Market may take steps to de- list our common stock or warrants. On August 31, 2022, we received written notice from the Listing Qualifications Department of The Nasdaq Stock Market LLC (the " Staff ") notifying us that for the preceding 30 consecutive business days (July 20, 2022 through August 30, 2022), our common stock did not maintain a minimum closing bid price of $ 1. 00 per share (" Minimum Bid Price Requirement ") as required by Nasdaq Listing Rule 5550 (a) (2). On August 21, 2023, we, received a notice from the Staff notifying us that the Staff has determined that for 10 consecutive business days, from August 7, 2023 to August 18, 2023, the closing bid price of our common stock has been at $ 1. 00 per share or greater. Accordingly, the Staff determined that we had regained compliance with Nasdaq Listing Rule 5550 (a) (2) and that the matter was closed. On May 19, 2023, we received a letter from the Staff stating that we were not in compliance with Nasdaq Listing Rule 5550 (b) (1) because

our stockholders' equity of $ 1, 439, 848 as of March 31, 2023, as reported in the Company' s Quarterly Report on Form 10- Q filed with the SEC on May 12, 2023, was below the minimum requirement of $ 2, 500, 000. On August 22, 2023, we also received a notice from the Staff that we now complied with Nasdaq Listing Rule 5550 (b) (1), and that the matter was closed. On August 4, 2023, we effected a reverse stock split for the purpose of regaining compliance with Nasdaq' s listing requirements. On August 21, 2023, we received a notice from the Staff stating that it had determined that for 10 consecutive business days, from August 7, 2023 to August 18, 2023, the closing bid price of our common stock was at $ 1. 00 per share or greater. Accordingly, the Staff determined that we regained compliance with Nasdaq Listing Rule 5550 (a) (2) and that the matter is now closed. On November 21, 2023, we received a letter from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5550 (b) (1) because our stockholders' equity of $ 2, 339, 258 as of September 30, 2023, as reported in the Company' s Quarterly Report on Form 10- Q filed with the SEC on November 14, 2023, was below the minimum requirement of $ 2, 500, 000. On November 29, 2023, we received a letter from Nasdaq stating that based on the Current Report on Form 8- K that the Company filed with the Securities and Exchange Commission on November 28, 2023 it determined that we were in compliance with Nasdaq Listing Rule 5550 (b) (1). The letter further stated that if we ~~fail~~ **failed** to evidence compliance with Nasdaq Listing Rule 5550 (b) (1) upon filing of our next periodic report we ~~may~~ **might** be subject to delisting. At ~~that~~ **such** time, Nasdaq staff ~~will~~ **would** provide written notification to us and we ~~may~~ **might** then appeal the Staff' s determination to a Nasdaq Hearings Panel **. Our subsequent annual report on form 10- K, filed on April 1, 2024, disclosed stockholders' equity at a level which was in compliance with Nasdaq Listing Rule 5550 (b) (1) and the matter was closed** . In the event of a de- listing, we would take actions to restore our compliance with The Nasdaq Capital Market' s listing requirements, but we can provide no assurance that any such action taken by us would allow our common stock become listed again, stabilize the market price or improve the liquidity of our common stock, prevent our common stock from dropping below The Nasdaq Capital Market, minimum bid price requirement or prevent future non- compliance with The Nasdaq Capital Market' s listing requirements. The National Securities Markets Improvement Act of 1996, which is a federal statute, prevents or preempts the states from regulating the sale of certain securities, which are referred to as " covered securities. " Because our common stock is listed on The Nasdaq Capital Market, our common stock is covered securities. Although the states are preempted from regulating the sale of covered securities, the federal statute does allow the states to investigate companies if there is a suspicion of fraud, and, if there is a finding of fraudulent activity, then the states can regulate or bar the sale of covered securities in a particular case. Further, if we were to be delisted from The Nasdaq Capital Market, our common stock would cease to be recognized as covered securities and we would be subject to regulation in each state in which we offer our securities. We are ~~an~~ **a** " smaller reporting company, " and we cannot be certain if the reduced SEC reporting requirements applicable to smaller reporting companies will make our common stock less attractive to investors. We are a " smaller reporting company ", as defined in Regulation S- K. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will cease to be a smaller reporting company if we have (i) more than $ ~~250~~ **700** million in market value of our shares held by non- affiliates as of the last business day of our most recently completed second fiscal quarter or (ii) more than $ 100 million of annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter and a market value of our shares held by non- affiliates more than $ ~~700~~ **250** million as of the last business day of our second fiscal quarter ~~. Until January 1, 2024, we were an " emerging growth company, " and therefore we were able to take advantage of certain exemptions from various public company reporting requirements, including not being required to have our internal controls over financial reporting audited by our independent registered public accounting firm pursuant to Section 404 of the Sarbanes- Oxley Act of 2002 (the " Sarbanes- Oxley Act "), reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and any golden parachute payments. We were able to take advantage of these exemptions until January 1, 2024 when we were no longer an " emerging growth company. " In addition, the JOBS Act provides that an " emerging growth company " can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We had elected to use the extended transition period for complying with new or revised accounting standards under the JOBS Act. This election allows us to delay the adoption of new or revised accounting standards that have different effective dates for public and private companies until those standards apply to private companies. As a result of this election, our financial statements may not be comparable to companies that comply with public company effective dates. We remained an " emerging growth company " until the last day of the fiscal year following the fifth anniversary of the completion of our initial public offering. References herein to " emerging growth company " have the meaning associated with that term in the JOBS Act~~ . We intend to take advantage of exemptions from various reporting requirements that are applicable to most other public companies, whether or not they are classified as " emerging growth companies, " including, but not limited to, an exemption from the provisions of Section 404 (b) of Sarbanes- Oxley requiring that our independent registered public accounting firm provide an attestation report on the effectiveness of our internal control over financial reporting. An attestation report by our auditor would require additional procedures by them that could detect problems with our internal control over financial reporting that are not detected by management. If our system of internal control over financial reporting is not determined to be appropriately designed or operating effectively, it could require us to restate financial statements, cause us to fail to meet reporting obligations, and cause investors to lose confidence in our reported financial information. The JOBS Act also provides that an " emerging growth company " can take advantage of the extended transition period provided in the Securities Act, for complying with new or revised accounting standards. However, we have chosen to " opt out " of this extended transition period and, as a result, we will comply with new or revised accounting standards on or prior to the relevant dates on which adoption of such standards is required for all public companies that are not emerging growth companies. Our decision to opt out of the extended transition period for complying with new or revised accounting standards is irrevocable. We cannot predict if investors will find our common stock less attractive because we have

relied, and intend to rely on, certain of these exemptions and benefits. As a result of being a public company, we are subject to additional reporting and corporate governance requirements that will require additional management time, resources and expense. As a public company, and particularly since we are no longer an emerging growth company, we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes- Oxley Act, the Dodd- Frank Wall Street Reform and Consumer Protection Act, the listing requirements of The Nasdaq Capital Market and other applicable securities rules and regulations impose various requirements on public companies, including the obligation to file with the SEC annual and quarterly information and other reports that are specified in the Securities Exchange Act of 1934, as amended (the " Exchange Act "), and to establish and maintain effective disclosure and financial controls and corporate governance practices. Our management and other personnel need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and will make some activities more time-consuming and costly. We cannot predict or estimate the amount of additional costs we may incur or the timing of such costs. 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 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. Our common stock has often been thinly traded, so you may be unable to sell at or near ask prices or at all if you need to sell your shares to raise money or otherwise desire to liquidate your shares. To date, there have been many days on which limited trading of our common stock took place. We cannot predict the extent to which investors' interests will lead to an active trading market for our common stock or whether the market price of our common stock will be volatile. If an active trading market does not develop, investors may have difficulty selling any of our common stock that they buy. We are likely to be too small to attract the interest of many brokerage firms and analysts. We cannot give you any assurance that an active public trading market for our common stock will develop or be sustained. The market price of our common stock could be subject to wide fluctuations in response to quarterly variations in our revenues and operating expenses, announcements of new products or services by us, significant sales of our common stock, including " short " sales, the operating and stock price performance of other companies that investors may deem comparable to us, and news reports relating to trends in our markets or general economic conditions. Our stock price has fluctuated in the past, has recently been volatile and may be volatile in the future, and as a result, investors in our common stock could incur substantial losses. The trading price of our common stock has been and is expected to continue to be volatile and has been and may continue to be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. On ~~March~~ **February** 28, ~~2024~~ **2025**, the reported low sale price of our common stock was $ ~~1~~ **0**. ~~31~~ **75**, the reported high sale price was $ ~~1~~ **0**. ~~43~~ **80** and closing price of our common stock was $ ~~1~~ **0**. ~~33~~ **79** while on December ~~29~~ **31**, ~~2023~~ **2024** ~~(the last day of trading in 2023)~~ the closing price of our common stock was $ ~~1~~ **0**. ~~86~~ **78**. We may incur rapid and substantial decreases in our stock price in the foreseeable future that are unrelated to our operating performance for prospects. In addition to the factors discussed in this " Risk Factors " section and elsewhere in this Annual Report, these factors include: ● the commencement, enrollment or any future clinical trials we may conduct, or changes in the development status of AD04 or any product candidates; ● any delay in our regulatory filings for our product candidate and any adverse development or perceived adverse development with respect to the applicable regulatory authority' s review of such filings, including without limitation the FDA' s issuance of a " refusal to file " letter or a request for additional information; ● adverse results or delays in clinical trials; ● our decision to initiate a clinical trial, not to initiate a clinical trial or to terminate an existing clinical trial; ● adverse regulatory decisions, including failure to receive regulatory approval of our product candidate; ● changes in laws or regulations applicable to our products, including but not limited to clinical trial requirements for approvals; ● adverse developments concerning our manufacturers; ● our inability to obtain adequate product supply for any approved product or inability to do so at acceptable prices; ● our inability to establish collaborations if needed; ● our failure to commercialize AD04; ● additions or departures of key scientific or management personnel; ● unanticipated serious safety concerns related to the use of AD04; ● introduction of new products or services offered by us or our competitors; ● announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments by us or our competitors; ● our ability to effectively manage our growth; ● the size and growth of our initial target markets; ● our ability to successfully treat additional types of indications or at different stages; ● actual or anticipated variations in quarterly operating results; ● our cash position; ● our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public; ● publication of research reports about us or our industry, or positive or negative recommendations or withdrawal of research coverage by securities analysts; ● changes in the market valuations of similar companies; ● overall performance of the equity markets; ● sales of our common stock by us or our stockholders in the future; ● trading volume of our common stock and declines in the market prices of stocks generally; ● changes in accounting practices; ● ineffectiveness of our internal controls; ● disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our or our licensee' s technologies; ● significant lawsuits, including patent or stockholder litigation; ● general political and economic conditions; and ● other events or factors, many of which are beyond our control, including those resulting from such events, or the prospect of such events, including war, terrorism and other international conflicts, including the conflict in Eastern Europe, public health issues including health epidemics or pandemics, such as the recent outbreak of the novel coronavirus (COVID- 19), and natural disasters such as fire, hurricanes, earthquakes, tornados or other adverse weather and climate conditions, whether occurring in the United States or elsewhere, could disrupt our operations, disrupt the operations of our suppliers or result in political or economic instability. In addition, the stock market in general, and The Nasdaq Capital Market and 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. Since the stock price of our common stock has fluctuated in the

past, has recently been volatile and may be volatile in the future, investors in our common stock could incur substantial losses. 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. Our need for future financing may result in the issuance of additional securities which will cause investors to experience dilution. Our cash requirements may vary from those now planned depending upon numerous factors, including the result of future research and development activities. We will require additional funds in the future to complete our clinical trials of AD04. There are no other commitments by any person for future financing. In addition, the issuance of securities in any future financing using our securities may dilute an investor' s equity ownership. Moreover, we may issue derivative securities, including options and / or warrants, from time to time, to procure qualified personnel or for other business reasons. The issuance of any such derivative securities, which is at the discretion of our board of directors, may further dilute the equity ownership of our stockholders. No assurance can be given as to our ability to procure additional financing, if required, and on terms deemed favorable to us. To the extent additional capital is required and cannot be raised successfully, we may then have to limit our then current operations and / or may have to curtail certain, if not all, of our business objectives and plans. The application of the " penny stock " rules to our common stock could limit the trading and liquidity of the common stock, adversely affect the market price of our common stock and increase your transaction costs to sell those shares. If our common stock is no longer listed on The Nasdaq Capital Market and becomes traded on a securities market or exchange which is not registered as a national securities exchange with the SEC under Section 6 of the Exchange Act, as long as the trading price of our common stock is below $ 5 per share, the open- market trading of our common stock will be subject to the " penny stock " rules, unless we otherwise qualify for an exemption from the " penny stock " definition. The " penny stock " rules impose additional sales practice requirements on certain broker- dealers who sell securities to persons other than established customers and accredited investors (generally those with assets in excess of $ 1. 0 million or annual income exceeding $ 200, 000 or $ 300, 000 together with their spouse). These regulations, if they apply, require the delivery, prior to any transaction involving a penny stock, of a disclosure schedule explaining the penny stock market and the associated risks. Under these regulations, certain brokers who recommend such securities to persons other than established customers or certain accredited investors must make a special written suitability determination regarding such a purchaser and receive such purchaser' s written agreement to a transaction prior to sale. These regulations may have the effect of limiting the trading activity of our common stock, reducing the liquidity of an investment in our common stock and increasing the transaction costs for sales and purchases of our common stock as compared to other securities. The stock market in general and the market prices for penny stock companies in particular, have experienced volatility that often has been unrelated to the operating performance of such companies. These broad market and industry fluctuations may adversely affect the price of our stock, regardless of our operating performance. Stockholders should be aware that, according to SEC Release No. 34- 29093, the market for penny stocks has suffered in recent years from patterns of fraud and abuse. Such patterns include: (i) control of the market for the security by one or a few broker- dealers that are often related to the promoter or issuer; (ii) manipulation of prices through prearranged matching of purchases and sales and false and misleading press releases; (iii) boiler room practices involving high- pressure sales tactics and unrealistic price projections by inexperienced sales persons; (iv) excessive and undisclosed bid- ask differential and markups by selling broker- dealers; and (v) the wholesale dumping of the same securities by promoters and broker- dealers after prices have been manipulated to a desired level, along with the resulting inevitable collapse of those prices and with consequent investor losses. The occurrence of these patterns or practices could increase the volatility of our share price. Provisions in our corporate charter documents and under Delaware law could make an acquisition of our company, 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 corporate charter and our bylaws may discourage, delay or prevent a merger, acquisition or other change in control of our company that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your 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 of directors is responsible for appointing the members of our management team, these provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors. Among other things, these provisions: ● our board of directors is divided into three classes, one class of which is elected each year by our stockholders with the directors in each class to serve for a three- year term; ● the authorized number of directors can be changed only by resolution of our board of directors; ● directors may be removed only by the affirmative vote of the holders of at least sixty percent (60 %) of our voting stock, whether for cause or without cause; ● our bylaws may be amended or repealed by our board of directors or by the affirmative vote of sixty- six and two- thirds percent (66 2 / 3 %) of our stockholders; ● stockholders may not call special meetings of the stockholders or fill vacancies on the board of directors; ● our board of directors will be authorized to issue, without stockholder approval, preferred stock, the rights of which will be determined at the discretion of the board of directors and that, if issued, could operate as a " poison pill " to dilute the stock ownership of a potential hostile acquirer to prevent an acquisition that our board of directors does not approve; ● our stockholders do not have cumulative voting rights, and therefore our stockholders holding a majority of the shares of common stock outstanding will be able to elect all of our directors; and ● our stockholders must comply with advance notice provisions to bring business before or nominate directors for election at a stockholder meeting. 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 us 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. Our Certificate of Incorporation and our bylaws provide that the Court of Chancery of the State of Delaware will be the exclusive forum for

certain types of state actions 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 Certificate of Incorporation and our bylaws provide that, unless we consent to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for (i) any derivative action or proceeding brought on behalf of us, (ii) 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, (iii) any action arising pursuant to any provision of the DGCL or our certificate of incorporation or bylaws (as either may be amended from time to time), or (iv) any action asserting a claim governed by the internal affairs doctrine. The exclusive forum provision does not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act or any other claim for which the federal courts have exclusive jurisdiction. To the extent that any such claims may be based upon federal law claims, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all suits brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Furthermore, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. These exclusive- forum provisions may limit a stockholder' s ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, employees, control persons, underwriters, or agents, which may discourage lawsuits against us and our directors, employees, control persons, underwriters, or agents. Additionally, a court could determine that the exclusive forum provision is unenforceable, and our stockholders will not be deemed to have waived our compliance with the federal securities laws and the rules and regulations thereunder. If a court were to find these provisions of our bylaws 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, financial condition, or results of operations. If securities or industry analysts do not publish research or publish inaccurate or unfavorable research about our business, our stock price and trading volume could decline. The trading market for our common stock will depend in part on the research and reports that securities or industry analysts publish about us or our business. Securities and industry analysts do not currently, and may never, publish research on our company. If no securities or industry analysts commence coverage of our company, the trading price for our stock would likely be negatively impacted. In the event securities or industry analysts initiate coverage, if one or more of the analysts who covers us downgrades our stock or publishes inaccurate or unfavorable research about our business, our stock price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our stock could decrease, which might cause our stock price and trading volume to decline. The warrants that we have issued are speculative in nature. The warrants that we have issued do not confer any rights of common stock ownership on their holders except as otherwise provided in the warrants. Specifically, commencing on the date of issuance, holders of the warrants may exercise their right to acquire the common stock and pay the exercise price to acquire the warrants. There can be no assurance that the market value of the warrants will equal or exceed their public offering price. In the event our common stock price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value. Holders of the warrants will have no rights as a common stockholder except as otherwise provided in the warrants until they acquire our common stock. Until holders of warrants acquire shares of our common stock upon exercise of their warrants, they will have no rights with respect to shares of our common stock issuable upon exercise of their warrant except as otherwise provided in the warrant. Upon exercise of a warrant, a holder will be entitled to exercise the rights of a common stockholder as to the security exercised only as to matters for which the record date occurs after the exercise. There is no established market for the warrants. There is no established trading market for the warrants. We have not applied for the listing of such warrants on any national securities exchange or other trading market. Without an active trading market, the liquidity of the warrants will be limited. Item 1B. Unresolved Staff Comments.