UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Fiscal Year Ended April 30 , 2024

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF

For the transition period from _____ to _____

Commission file number 001-40483

ALZAMEND NEURO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**81-1822909**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)

3480 Peachtree Road NE , Second Floor Suite 103 , Atlanta , GA	**30326**	**(844) 722-6333**
(Address of principal executive offices)	(Zip Code)	(Registrant's telephone number, including area code)

Securities registered under Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**ALZN**	**NASDAQ Capital Market**

Securities registered under Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes ☐ No x

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding year (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes x No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐
Non-accelerated filer x
Emerging growth company x

Accelerated filer ☐
Smaller reporting company x

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No x

The aggregate market value of the common stock held by non-affiliates of the registrant, based on the closing price of the shares of common stock on October 31, 2023 (the last business day of the registrant's most recently completed second fiscal quarter), as reported by The Nasdaq Stock Market LLC on such date was approximately $ 6.7 million. Shares of the registrant's common stock held by each executive officer and director and by each other person who may be deemed to be an affiliate of the registrant have been excluded from this computation. This calculation does not reflect a determination that certain persons are affiliates of the registrant for any other purpose.

There were 841,240 shares of common stock outstanding as of July 29, 2024.

Documents incorporated by reference: None

ALZAMEND NEURO, INC.

FORM 10-K

FOR THE FISCAL YEAR ENDED APRIL 30, 2024

INDEX

NOTE ABOUT FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K (the "Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, and Section 21E of the Securities Exchange Act of 1934, as amended. These statements relate to future events or our future financial performance. We have attempted to identify forward-looking statements by terminology including "anticipates," "believes," "expects," "can," "continue," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predict," "should" or "will" or the negative of these terms or other comparable terminology. These statements are only predictions; uncertainties and other factors may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels or activity, performance or achievements expressed or implied by these forward-looking statements. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance or achievements. Our expectations are as of the date this Annual Report is filed, and we do not intend to update any of the forward-looking statements after the date this Annual Report is filed to confirm these statements to actual results, unless required by law.

This Annual Report also contains estimates and other statistical data made by independent parties and by us relating to market size and growth and other industry data. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified the statistical and other industry data generated by independent parties and contained in this Annual Report and, accordingly, we cannot guarantee their accuracy or completeness, though we do generally believe the data to be reliable. In addition, projections, assumptions and estimates of our future performance and the future performance of the industries in which we operate are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" and elsewhere in this Annual Report. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

RISK FACTOR SUMMARY

Below is a summary of the principal factors that make an investment in our common stock speculative. This summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Annual Report and our other filings with the Securities and Exchange Commission (the "SEC"), before making investment decisions regarding our common stock.

- We need to obtain substantial additional funding to complete the development and any commercialization of AL001 and ALZN002. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs or other operations.
- We are at an early stage of clinical development and currently have no source of near-term revenue and may never become profitable.
- We have a limited operating history on which to judge our business prospects and management.
- We have both operational and financial milestones that must be met to maintain the licensing rights to our current technology and intellectual property from the University of South Florida Research Foundation.
- If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with the Licensor, we could lose license rights that are important to our business.

- We are substantially dependent on the success of our product candidates, which may not receive regulatory approval or be successfully commercialized.
- Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of AL001 or ALZN002, or limit the scope of any approved label or market acceptance.
- Development and regulatory approval of our drug candidates present a number of risks, which are delineated in the Risk factors section.
- If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop AL001, ALZN002 or any future product candidates, conduct our in-licensing and development efforts or commercialize AL001, ALZN002 or any of our future product candidates.
- Our intellectual property rights present a number of risks.

- Our affiliates and related party transactions present a number of risks.
- If we do not regain compliance with or continue to satisfy the Nasdaq Capital Market continued listing requirements, our common stock could be delisted from the Nasdaq Capital Market.
- The market price of our common stock is volatile, which could result in substantial losses for investors.
- The concentration of our stock ownership will limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.
- We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

PART I

ITEM 1. BUSINESS

In this Annual Report, unless the context requires otherwise, references to the “Company,” “Alzamend,” “we,” “our company” and “us” refer to Alzamend Neuro, Inc., a Delaware corporation and its subsidiary.

Company Overview

We are a clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer’s disease (“Alzheimer’s”), bipolar disorder (“BD”), major depressive disorder (“MDD”) and post-traumatic stress disorder (“PTSD”). With our two product candidates, we aim to bring treatments or potential cures to market as quickly as possible. Far too many individuals, patients and caregivers suffer from the burden created by these devastating, and often fatal, diseases. Our primary target, Alzheimer’s, is among the most-feared diseases (second only to cancer) among Americans, according to a 2023 Center for Disease Control survey. Alzheimer’s is also the seventh leading cause of death (in 2020 and 2021) in the United States (“U.S.”) according to a 2024 report from the Alzheimer’s Association, a nonprofit that funds research. Existing Alzheimer’s treatments only temporarily relieve symptoms and while one treatment has been shown to slow the progression of the disease, none had been shown to halt the progression of the disease, which currently affects roughly 6.9 million Americans, and that number is expected to grow to 13 million individuals by 2050. Alzheimer’s also impacts more than 11 million Americans who provide an estimated 18 billion hours of unpaid care per year, according to data provided by the Alzheimer’s Association. In 2024, the estimated healthcare costs for treating individuals with Alzheimer’s in the U.S. will be $360 billion, including $231 billion in Medicare and Medicaid payments. These costs could rise to as high as $1 trillion per year by 2050 if no permanent treatment or cure for Alzheimer’s is found, according to the Alzheimer’s Association.

Our pipeline consists of two novel therapeutic drug candidates:

- AL001 - A patented ionic cocrystal technology delivering a therapeutic combination of lithium, salicylate and proline through three royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc., as licensor (the “Licensor”); and
- ALZN002 - A patented method using a mutant peptide sensitized cell as a cell-based therapeutic vaccine that seeks to restore the ability of a patient’s immunological system to combat Alzheimer’s through a royalty-bearing exclusive worldwide license from the Licensor.

Our most advanced product candidate (lead product) is licensed and in clinical development in humans is AL001, an ionic cocrystal of lithium for the treatment of Alzheimer’s, BD, MDD and PTSD. Based on our preclinical data involving mice models, AL001 treatment prevented cognitive deficits, depression and irritability and is superior in improving associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of AL001 for the treatment of Alzheimer’s, BD, MDD and PTSD in humans. Lithium was the first mood stabilizer approved by the U.S. Food and Drug Administration (“FDA”) and is still a first-line treatment option (considered the “gold standard”) for BD and is prescribed off-label for MDD and PTSD. Moreover, lithium has been marketed for more than 35 years and human toxicology regarding its use has been well characterized, potentially mitigating the regulatory burden for safety data.

The results of randomized, placebo-controlled, clinical trials of lithium in the treatment of patients with Alzheimer’s dementia and subjects with mild cognitive impairment have been widely published. Clinical studies have indicated that lithium administered at doses lower than those used for affective disorders can favorably impact Alzheimer’s outcomes. A study by O.V. Forlenza, et al., entitled “Disease-Modifying Properties of Long-Term Lithium Treatment for Amnestic Mild Cognitive Impairment: Randomized Controlled Trial,” which appeared in the British Journal of Psychiatry (2011), reported that lithium was superior to a placebo, evidencing a slower decline of cognitive function as measured by the Alzheimer’s Disease Assessment Scale cognitive subscale. Given the absence of adequate, widely adopted treatments that can slow, halt or even reverse the decline of this highly prevalent disease, the potential efficacy of lithium in the long-term management of Alzheimer’s may positively impact public health. There is an unmet medical need for safe and effective Alzheimer’s treatments, particularly for treatments with neuroprotective properties.

There is increasing evidence to suggest that depressive illness, particularly in the elderly, is associated with neuronal cell loss. These findings suggest that lithium may exert some long-term beneficial effects in the treatment of affective disorders via underappreciated neuroprotective effects. Molecular biology and animal studies have also indicated that lithium may offer protection against Alzheimer's. Given the absence of other adequate treatments, we believe that research and commercialization of the potential efficacy of lithium in the long-term treatment of neurodegenerative disorders is well worth pursuing.

Our Business Strategy

We intend to develop and commercialize therapeutics that are better than existing treatments and have the potential to significantly improve the lives of individuals afflicted by Alzheimer's, BD, MDD and PTSD. To achieve these goals, we are pursuing the following key business strategies:

- **Advance clinical development of AL001 for Alzheimer's, BD, MDD and PTSD treatment** . We completed our Phase I clinical trial in March 2022 and initiated a Phase IIA Multiple Ascending Dose ("MAD") clinical trial in May 2022. We completed the clinical portion of the Phase IIA MAD clinical trial in March 2023 and reported topline data in June 2023. We announced that we successfully identified a maximum tolerated dose ("MTD") for development of AL001, as assessed by an independent safety review committee. This MTD, providing lithium at a lithium carbonate equivalent dose of 240 mg 3-times daily, is designed to be unlikely to require lithium therapeutic drug monitoring ("TDM"). Also, this MTD mitigates risk in treatments for fragile populations, such as Alzheimer's patients. Additionally, we are investigating the potential of AL001 for patients suffering from BD, MDD and PTSD, and submitted several Investigational New Drug ("IND") applications to the FDA for these indications: (i) the IND for BD was submitted in August 2023 and we received a "study may proceed" letter from the FDA in September 2023; (ii) the IND for MDD was submitted in October 2023 and we received a "study may proceed" letter from the FDA in November 2023; and (iii) the IND for PTSD was submitted in November 2023 and we received a "study may proceed" from the FDA in December 2023. If we achieve successful Phase III clinical trials in humans, we intend to seek approval to commercialize AL001 via a New Drug Application ("NDA");

- **Advance clinical development of ALZN002 for Alzheimer's treatment.** We submitted an IND application to the FDA in September 2022, and received a "study may proceed" letter in October 2022. In April 2023, we initiated a Phase I/IIA clinical trial for ALZN002 to treat mild to moderate dementia of the Alzheimer's type. If we achieve successful Phase III clinical trials in humans, we intend to seek approval to commercialize ALZN002 through a Biologics License Application ("BLA");

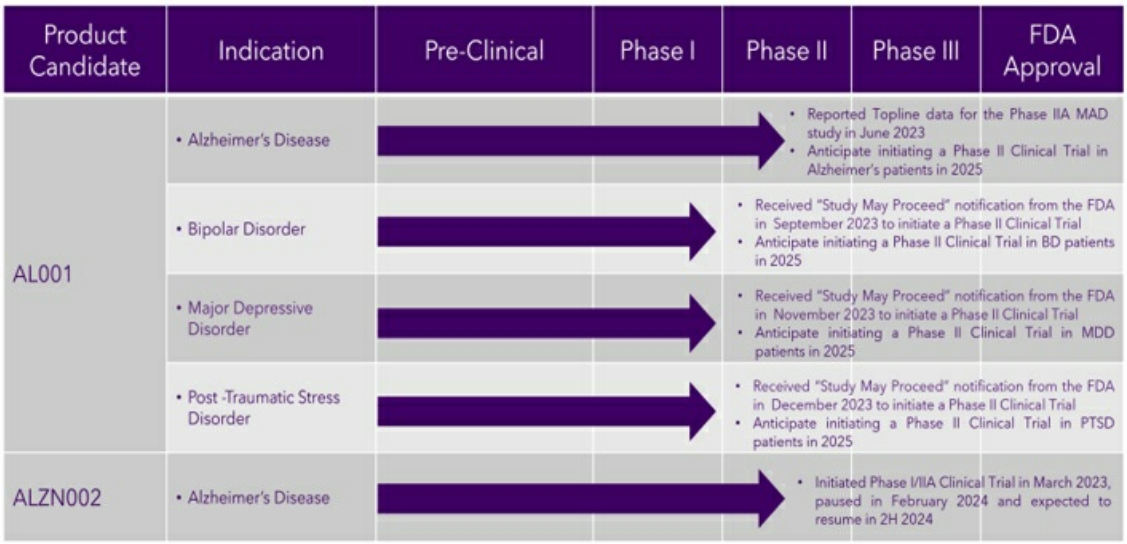
- **Expand our pipeline of pharmaceuticals to include additional delivery methods.** Another element of our business strategy is to explore, resources permitting, different formulations (liquid, immediate release and sprinkle capsules) to deliver AL001 to accommodate the needs of patients afflicted with Alzheimer's, BD, MDD and PTSD;

- **Focus on translational and functional endpoints to efficiently develop product candidates.** We believe that AL001 is positioned for a Section 505(b)(2) regulatory pathway for new drug approvals. We also believe that AL001 and ALZN002 are positioned for breakthrough therapy designations because of their positive effects on a pharmacodynamic biomarker (beta-amyloids) and potential for a clinically meaningful effect on Alzheimer's, making them eligible to receive assistance from the FDA throughout the approval process that may shorten the development timelines. However, we have neither received breakthrough therapy designation nor have we qualified for expedited development, and no assurance can be given that we will. Even if we qualify for breakthrough therapy designation or expedited development, it may not actually lead to faster development or expedited regulatory review and approval or necessarily increase the likelihood that we will ultimately receive FDA approval; and

- **Optimize the value of AL001 and ALZN002 in major markets** . We intend to commercialize AL001 and ALZN002 by seeking FDA marketing approval for both product candidates and partnering with biopharmaceutical companies seeking to strategically fortify pipelines and, in turn, receiving funding for the costly later-stage clinical development. We do not anticipate selling products directly into the marketplace, though we may do so depending on market conditions. Our focus is expected to concentrate on entering into strategic transactions with established distributors and producers, which will provide distribution and marketing capabilities for the sale of our products in the marketplace.

Our Development Pipeline

The following chart provides an overview of the current development stages of our product candidates.



Our product candidates will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before either of them or any successors are likely to provide us with any revenue. As a result, if we do not successfully develop, achieve regulatory approval for and commercialize our product candidates, our long-term business plans will not materialize, and we will be unable to generate the revenue we have forecast for the foreseeable future, if any. We do not anticipate that we will generate our maximum revenue for several years, or that we will achieve profitability for any of our therapeutic drug candidates until at least a few years after generating material revenue, if at all. If we are unable to generate revenue or raise substantial additional capital, we will not be able to pursue any expansion of our business or acquire additional intellectual property, we will never become profitable, and we will be unable to continue our operations at the currently planned pace, if at all.

AL001 Drug Candidate

Our lead product candidate that we have licensed and begun clinical development of in humans is an ionic cocrystal of lithium for the treatment of Alzheimer's, BD, MDD and PTSD. Lithium salts have a long history of human consumption beginning in the 1800s. In psychiatry, they have been used to treat mania and as a prophylactic for depression since the mid-20th century. Today, lithium salts are used as a mood stabilizer for the treatment of BD. Although the FDA has approved no medications as safe and effective treatments for suicidality, lithium has proven to be the only drug that consistently reduces suicidality in patients with neuropsychiatric disorders. Despite these effective medicinal uses, current FDA-approved lithium pharmaceutics (lithium carbonate and lithium citrate) are limited by a narrow therapeutic window that requires regular blood monitoring of plasma lithium levels and blood chemistry by a clinician to mitigate adverse events. Because conventional lithium salts (carbonate and citrate) are eliminated relatively quickly, multiple administrations throughout the day are required to safely reach therapeutic plasma concentrations. Existing lithium drugs, such as lithium chloride and lithium carbonate, suffer from chronic toxicity, poor physicochemical properties, and poor brain bioavailability. Because lithium is so effective at reducing manic episodes in patients with BD, it is still used clinically despite its narrow therapeutic index. This has led researchers to begin to look for other treatment methods than lithium but that may evince similar bioactivities.

Scientists from the University of South Florida have developed a new lithium cocrystal composition and method of preparation that, under certain clinical and/or testing conditions, have been shown to allow for lower dosages to achieve therapeutic brain levels of lithium for psychiatric disorders, which could lead to a broadening of lithium's therapeutic index. Our studies and tests have indicated that the compound offers improved physiochemical properties compared to existing forms of lithium, giving it the potential to be developed as an anti-suicidal drug and for use against mood disorders.

Recent evidence suggests that lithium may be efficacious for both the treatment and prevention of Alzheimer's. Unlike traditional medications, which only address a single therapeutic target, lithium appears to be neuroprotective through several modes of action. For example, recent studies have indicated that it exerts neuroprotective effects, in part, by increasing a brain-derived neurotrophic factor leading to restoration of learning and memory. Another neuroprotective mechanism of lithium indicated by recent studies is the attenuation of the production of inflammatory cytokines like IL-6 and nitric oxide in activated microglia. Results from recent clinical studies suggest that lithium treatment may reduce the progression of dementia while preserving cognitive function and reducing biomarkers associated with Alzheimer's.

AL001, the novel ionic cocrystal of lithium, which was designed, synthesized and characterized by a team of inventors from the University of South Florida, has been shown to exhibit improved nonclinical pharmacokinetics compared to currently available FDA-approved lithium products and is also bioactive in many in vitro models of Alzheimer's. AL001 may constitute a means of treating Alzheimer's, BD, MDD and PTSD.

We believe that our ability to re-engineer lithium in solid dosage forms in order to optimize performance has the potential to address a wide range of clinical applications ranging from neurodegenerative disorders, not merely Alzheimer's, but also amyotrophic lateral sclerosis (known as ALS and popularly referred to as Lou Gehrig's disease), Huntington's disease, multiple sclerosis, Parkinson's disease and traumatic brain injury, to more psychiatric conditions such as BD, MDD, mania, PTSD and suicidality. This novel approach is intended to achieve the desired therapeutic outcome of enhanced penetration through the blood-brain barrier and sustained brain lithium concentrations while systemic exposures (and toxicities) are mitigated for other organ systems. The optimal modified-release lithium dosing approach for AL001 should avoid acutely toxic peak concentrations in blood, as well as in the brain, and should maintain such relatively minor blood concentrations for a predictable, clinically relevant time, with overall low systemic exposures that mitigate the potential for adverse events. We anticipate that the lithium delivery system will be adaptable to a dosing regimen that maintains therapeutic brain lithium concentrations consistently for the longest possible time while allowing only modest exposures and providing adequate recovery periods between doses for other organ systems.

Clinical Trials

Phase I Study

On September 13, 2021, we initiated a randomized, balanced, Phase I, single-dose, open-label, two-treatment, two-period, two- sequence, crossover, relative bioavailability clinical trial to investigate lithium pharmacokinetics and safety of AL001 formulation compared to a marketed immediate release lithium carbonate formulation in healthy subjects. The primary objective of this clinical trial was to assess the relative bioavailability of the AL001 lithium formulation relative to a marketed lithium carbonate formulation in healthy subjects for the purpose of determining potential clinically safe and effective AL001 dosing in future studies. Additionally, we wanted to characterize safety and tolerability of the tested formulations under the conditions of

this clinical trial. This was a first-in-human clinical trial of the AL001 formulation and this trial was designed to assess the relative bioavailability of the AL001 lithium formulation compared to a marketed lithium carbonate formulation in at least 24 completed healthy subjects (30 subjects were to be enrolled) for the purpose of determining potential clinically safe and effective AL001 dosing in future clinical trials. The AL001 lithium content was nearly half of the reference lithium carbonate capsule dosage as it was expected that treatment of frail Alzheimer's patients will require half the lithium dose used for treatment of BD. Lithium carbonate 300 mg (Reference product) was given as a single dose in this clinical trial; this is often used as a starting dose for treatment of BD when given three times daily. The shape of the AL001 lithium plasma concentration versus time curve was unknown prior to this study. Also unknown were the AL001 rate and extent of lithium absorption. The Phase I study was completed in March 2022 with the following results:

- AL001 was shown to be safe and well-tolerated in healthy adult subjects;
- No death or serious adverse events were reported during the trial;
- The safety profiles of both AL001 and the marketed lithium carbonate capsule were benign;
- No clinically significant abnormal findings in electrocardiograms were noted during the trial;
- AL001 salicylate plasma concentrations were observed to be well tolerated and consistently within safe limits; and
- Dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicated that AL001, at a lithium carbonate equivalent dose of 150 mg, is bioequivalent to a marketed 300 mg lithium carbonate capsule and the shapes of the lithium plasma concentration versus time curves are similar.

Phase IIA Study

On May 5, 2022, we initiated a multiple-dose, steady-state, double-blind, ascending dose safety, tolerability, pharmacokinetic clinical trial (www.clinicaltrials.gov, identifier: NCT05363293) of AL001 in patients with mild to moderate Alzheimer's and healthy subjects with the following objectives:

- **Primary:** To evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions in Alzheimer's patients and healthy subjects;

- **Secondary:** To characterize the MTD of AL001 in patients with mild to moderate Alzheimer's and healthy subjects; and
- **Exploratory:** Determination of qualitative and quantitative evaluations of patients with Alzheimer's and healthy subjects desirable characteristics for future Phase II and III clinical studies in order to:
    - Facilitate recruitment into subsequent AL001 clinical trials; and
    - Facilitate trial-adherence to completion of study requirements including treatment adherence.

We completed the Phase IIA clinical trial in March 2023 and announced positive topline data in June 2023. We announced that we successfully identified an MTD for development of AL001 from a multiple-ascending dose study as assessed by an independent safety review committee. This dose, providing lithium at a lithium carbonate equivalent dose of 240 mg 3-times daily ("TID"), is designed to be unlikely to require lithium TDM. Also, this MTD is risk mitigated for the purpose of treating fragile populations, such as Alzheimer's patients.

Lithium is a commonly prescribed drug for manic episodes in BD type 1 as well as maintenance therapy of BP in patients with a history of manic episodes. Lithium is also prescribed off-label for MDD, BD and treatment of PTSD, among other disorders. Lithium was the first mood stabilizer approved by the FDA and is still a first-line treatment option (considered the "gold standard") but is underutilized, perhaps because of the need for TDM. Lithium was the first drug that required TDM by regulatory authorities in product labelling because the effective and safe range of therapeutic drug blood concentrations is narrow and well defined for treatment of BP when using lithium salts. Excursions above this range can be toxic, and dosages below it can impair effectiveness.

Planned Future Studies

We intend to initiate clinical trials at the MTD to determine relative increased lithium levels in the brain compared to a marketed lithium salt for BD, MDD and PTSD, based on published mouse studies that predict that lithium can be given at lower doses for equivalent therapeutic benefit when treating with AL001. For example, the goal is to replace a 300 mg TID lithium carbonate dose for treatment of BD with a 240 mg TID AL001 lithium equivalent, which represents a daily decrease of 20% of lithium given to a patient. We will also include cohorts of healthy subjects and Alzheimer's patients. We anticipate partnering with a reputable research institution for the study in the second half of 2024.

Based on the results from our Phase IIA MAD study for AL001, we also plan to initiate two safety and efficacy clinical trials in subjects with mild to moderate dementia of the Alzheimer's type. These studies would most likely commence after the "lithium in brain" study.

ALZN002 Drug Candidate

The other product candidate that we have licensed to clinically develop in humans is ALZN002, a patented method using a mutant peptide sensitized cell as a cell-based therapeutic vaccine which seeks to restore the ability of the patient's immunological system to combat Alzheimer's. The proposed mechanism of action is through the pulsed-Dendritic Cell ("DC") activation of T-cells that stimulates the immune system, resulting in the clearance of brain amyloid. Preclinical studies conducted from April 2005 to July 2010 demonstrated that the infusion of transgenic (or genetically modified) mice with ALZN002-pulsed DCs is associated with lower amyloid burden and improved neuro-behavioral performance. This is likely to be mediated by an anti-inflammatory effect in addition to the immunogenicity of this therapy.

The development of ALZN002 is predicated on the theory that Alzheimer's symptoms may be caused in large part by plaque deposits that can cluster in the brain composed of protein fragments called beta-amyloids that build up between nerve cells. One hypothesis is that a special type of immune cell, natural beta-amyloid antibodies, may play a role in preventing plaque build-up in people without Alzheimer's. As people age, their immune systems may degrade, and some people may be unable to produce natural beta-amyloid antibodies, the absence of which leads to the plaque build-up causing Alzheimer's.

ALZN002 is intended to elicit an immune response to produce anti-amyloid antibodies, which can then neutralize circulated beta-amyloids and prevent additional plaque build-up. The mutant antigen within ALZN002 was selected specifically for its high human leukocyte antigens binding affinity, thereby avoiding the need for an adjuvant, which may cause an adverse (Th1) immune response.

ALZN002 is an autologous modified DC treatment. More precisely, it is a patient-specific therapy where the patient undergoes leukapheresis, a

nonsurgical treatment used to reduce the quantity of white blood cells in the bloodstream, to isolate peripheral blood monocytes that are subsequently matured into DCs using cytokine therapy (IL4+ GM-CSF) cocktail. The DCs are incubated with a modified amyloid beta (Aβ) peptide to sensitize them, and then administered to the same patient.

Significant evidence has accumulated recently suggesting that immunotherapy is a highly promising modality of treatment in Alzheimer's. Most current immune-based active investigations are focused on passive immunization by pre-prepared Aβ antibody administration. Active immunization may offer additional or more lasting effects on the clearance of amyloid and a safer approach due to its reliance on autologous immune mechanisms. Further, preliminary evidence suggests a recurrence of the amyloid accumulation after clearance with the immunoglobulins. A prior attempt at engaging the immune system to treat Alzheimer's was conducted using the immunization with pre-aggregated synthetic Aβ (AN-1792) combined with the immunogenic adjuvant QS-21. The Phase IIA study with AN-1792 was terminated by the FDA due to severe meningoencephalitis in approximately 6% of vaccinated subjects. We believe that this may have been caused by using a QS-21 adjuvant in the vaccine formulation.

Clinical Trials

Pre-Clinical

On July 23, 2021, we announced that Alzamend received positive toxicology results for ALZN002 in a good laboratory practices ("GLP") toxicology study using a transgenic mouse model of Alzheimer's. The study was conducted by Charles River Laboratories. ALZN002 is a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic vaccine that seeks to restore the ability of a patient's immunological system to combat Alzheimer's.

A five-dose GLP study with ALZN002-sensitized cells was completed using a transgenic mouse model of Alzheimer's to investigate the tolerability of ALZN002. Single injections were administered on days 1, 30, 50, 70, and 90. The mice were evaluated for potential toxicity and reversibility of any findings at 75 and 90 days after the final dosing.

Histopathology results demonstrate that there was no indication of T-cell infiltration or meningoencephalitis, which suggests that ALZN002 therapy is safe and tolerable as there were no adverse findings over a 90-day period or 90 days after the last dose. There were no treatment-related mortalities or reports of adverse effects on clinical observations, body weight parameters, organ weight parameters, clinical pathology parameters, gross pathology observations, or histopathologic observations during the main study or the recovery phase.

Modified cell therapies, especially DCs, may provide a safer and more patient-specific active immunization. Ex-vivo modification of DCs as a modality of treatment has been previously used in oncological therapeutics. It has been shown to be relatively safe and capable of engaging the immune system to attack the target tissues with success. Its use in Alzheimer's therapeutics is relatively recent.

Phase I/II Study

We submitted a pre-IND meeting request for ALZN002 and supporting briefing documents to the Center for Biological Evaluation and Research of the FDA on July 30, 2021. We received a written response relating to the pre-IND from the FDA providing a path for Alzamend's planned clinical development of ALZN002 on September 30, 2021. The FDA agreed to allow Alzamend to submit an IND to conduct a combined Phase I/II study.

On September 28, 2022, we submitted an IND to the FDA for ALZN002 and received a "study may proceed" letter on October 31, 2022. The product candidate is an immunotherapy vaccine designed to treat mild to moderate dementia of the Alzheimer's type. ALZN002 is a proprietary "active" immunotherapy product, which means it is produced by each patient's immune system. It consists of autologous DCs consisting of activated white blood cells taken from each individual patient so that they can be engineered outside of the body to attack Alzheimer's-related amyloid-beta proteins. These DCs are pulsed with a novel amyloid-beta peptide (E22W) designed to bolster the ability of the patient's immune system to combat Alzheimer's; the goal is to foster tolerance to treatment for safety purposes while stimulating the immune system to reduce the brain's beta-amyloid protein burden, resulting in reduced Alzheimer's signs and symptoms. Compared to passive immunization treatment approaches that use foreign blood products (such as monoclonal antibodies), active immunization with ALZN002 is anticipated to offer a more robust and long-lasting effect on the clearance of amyloid. This approach could prove safer due to its reliance on autologous immune components, using each individual patient's own white blood cells rather than foreign cells and/or blood products.

On April 3, 2023, we announced the initiation of a Phase I/IIA clinical trial for ALZN002 to treat mild to moderate dementia of the Alzheimer's type. The purpose of this trial is to assess the safety, tolerability, and efficacy of multiple ascending doses of ALZN002 compared with that of a placebo in 20-30 subjects with mild to moderate morbidity. The primary goal of this clinical trial is to determine an appropriate dose of ALZN002 for treatment of patients with Alzheimer's in a larger Phase IIB efficacy and safety clinical trial. On February 13, 2024, we received notice from the company we engaged as our contract research organization ("CRO"), Biorasi, LLC ("Biorasi") that Biorasi was terminating our contract with them. We are currently pursuing the engagement of a replacement CRO.

Intellectual Property and Licensing Agreements

On July 2, 2018, we entered into two Standard Exclusive License Agreements with Sublicensing Terms for AL001 with the Licensor and its affiliate, the University of South Florida (the "AL001 Licenses"), pursuant to which the Licensor granted us a royalty bearing exclusive worldwide licenses limited to the field of Alzheimer's, under U.S. Patent Nos. (i) 9,840,521, entitled "Organic Anion Lithium Ionic Cocrystal Compounds and Compositions," filed September 24, 2015 and granted December 12, 2017, and (ii) 9,603,869, entitled "Lithium Co-Crystals for Treatment of Neuropsychiatric Disorders", filed May 21, 2016 and granted March 28, 2017. On February 1, 2019, we entered into the First Amendments to the AL001 Licenses, on March 30, 2021, we entered into the Second Amendments to the AL001 Licenses and on June 8, 2023, we entered into the Third Amendments to the AL001 Licenses (collectively, the "AL001 License Agreements"). The Third Amendments to the AL001 Licenses modified the timing of the payments for the license fees.

The AL001 License Agreements require that we pay combined royalty payments of 4.5% on net sales of products developed from the licensed technology for AL001. We have already paid an initial license fee of $200,000 for AL001. As an additional licensing fee for the license of the AL001 technologies, the Licensor received 14,853 shares of our common stock. Minimum royalties for AL001 License Agreements are $40,000 on the first anniversary of the first commercial sale, $80,000 on the second anniversary of the first commercial sale and $100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the AL001 License Agreements.

On May 1, 2016, we entered into a Standard Exclusive License Agreement with Sublicensing Terms for ALZN002 with the Licensor (the "ALZN002 License"), pursuant to which the Licensor granted us a royalty bearing exclusive worldwide license limited to the field of Alzheimer's

Immunotherapy and Diagnostics, under U.S. Patent No. 8,188,046, entitled “Amyloid Beta Peptides and Methods of Use”, filed April 7, 2009 and granted May 29, 2012. On August 18, 2017, we entered into the First Amendment to the ALZN002 License, on May 7, 2018, we entered into the Second Amendment to the ALZN002 License, on January 31, 2019, we entered into the Third Amendment to the ALZN002 License, on January 24, 2020, we entered into the Fourth Amendment to the ALZN002 License, on March 30, 2021, we entered into the Fifth Amendment to the ALZN002 License, on April 17, 2023, we entered into the Sixth Amendment to the ALZN002 License and on December 11, 2023, we entered into the Seventh Amendment to the ALZN002 License (collectively, the “ALZN002 License Agreement”). The Seventh Amendment to the ALZN002 License modified the timing of the payments for the license fees.

The ALZN002 License Agreement requires us to pay royalty payments of 4% on net sales of products developed from the licensed technology for ALZN002. We have already paid an initial license fee of $200,000 for ALZN002. As an additional licensing fee for the license of ALZN002, the Licensor received 24,012 shares of our common stock. Minimum royalties for ALZN002 are $20,000 on the first anniversary of the first commercial sale, $40,000 on the second anniversary of the first commercial sale and $50,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the ALZN002 License Agreement.

On November 19, 2019, we entered into two Standard Exclusive License Agreements with Sublicensing Terms for two additional indications of AL001 with the Licensor (the “November AL001 License”), pursuant to which the Licensor granted us a royalty bearing exclusive worldwide licenses limited to the fields of (i) neurodegenerative diseases excluding Alzheimer’s and (ii) psychiatric diseases and disorders. On March 30, 2021, we entered into the First Amendments to the November AL001 License and on April 17, 2023, we entered into the Second Amendments to the November AL001 License (collectively, the “November AL001 License Agreements”). The Second Amendments to the November AL001 License modified the timing of the payments for the license fees.

The November AL001 License Agreements require us to pay royalty payments of 3% on net sales of products developed from the licensed technology for AL001 in those fields. We paid an initial license fee of $20,000 for the additional indications. Minimum royalties for November AL001 License Agreements are $40,000 on the first anniversary of the first commercial sale, $80,000 on the second anniversary of the first commercial sale and $100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the November AL001 License Agreements.

These license agreements have an indefinite term that continue until the later of the date that no licensed patent under the applicable agreement remains a pending application or enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, or the date on which the licensee’s obligations to pay royalties expire under the applicable license agreement. Under our various license agreements, if we fail to meet a milestone by its specified date, Licensor may terminate the license agreement. The Licensor was also granted a preemptive right to acquire such shares or other equity securities that may be issued from time to time by us while the Licensor remains the owner of any equity securities of our company.

Additionally, we are required to pay milestone payments on the due dates to the Licensor for the license of the AL001 technologies and for the ALZN002 technology, as follows:

Original AL001 Licenses:

Payment	Due Date	Event
$ 50,000*	Completed September 2019	Pre-IND meeting
$ 65,000*	Completed June 2021	IND application filing
$ 190,000*	Completed December 2021	Upon first dosing of patient in a clinical trial
$ 500,000*	Completed March 2022	Upon completion of first clinical trial
$ 1,250,000	March 2025	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	8 years from the effective date of the agreement	Upon FDA NDA approval

* Milestone met and completed

ALZN002 License:

Payment	Due Date
$ 50,000*	Upon IND application - completed January 2022
$ 50,000	Upon first dosing of patient in first Phase I clinical trial
$ 500,000	Upon completion of first Phase IIB clinical trial
$ 1,000,000	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	Upon first commercial sale

* Milestone met and completed

Additional AL001 Licenses:

Payment	Due Date	Event
$ 2,000,000	March 2026	Upon first patient treated in a Phase III clinical trial
$ 16,000,000	August 1, 2029	First commercial sale

Market Opportunity

According to the National Institute of Health (“NIH”), there are more than 43.7 million Americans afflicted with Alzheimer’s, BD, MDD and PTSD. The rise in the prevalence of these diseases/disorders and the various risks, such as high stress, substance abuse, and advancements in a combination

of drugs are primarily propelling market growth. Advancements in technology allowing more accurate diagnosis/detection of Alzheimer's, BD, MDD, and PTSD are also positively influencing market growth. Other factors, such as increasing research and development activities (via clinical trials) and investments by the government to improve the healthcare industry, are expected to further drive market growth. Additionally, increased awareness about Alzheimer's, BD, MDD and PTSD via the various disease/disorder-specific non-profit organizations is accelerating market growth. The potential marketplace for a commercialized therapy or treatment would be tremendously significant with large financial support available from numerous national and international pharmaceutical companies and various governments and worldwide agencies. We were founded with a mission to further develop AL001 and ALZN002, by funding them through human clinical trials administered by the FDA and ultimately, if successful, making them available to the public.

Patient Population	AL001	ALZN002
Alzheimer's Disease	6.9 Million	6.9 Million
Bipolar Disorder ("BD")	7 Million	
Major Depressive Disorder ("MDD")	21 Million	
Post-Traumatic Stress Disorder ("PTSD")	9 Million	
Total Patient Population	43.9 Million	6.9 Million

Industry Overview

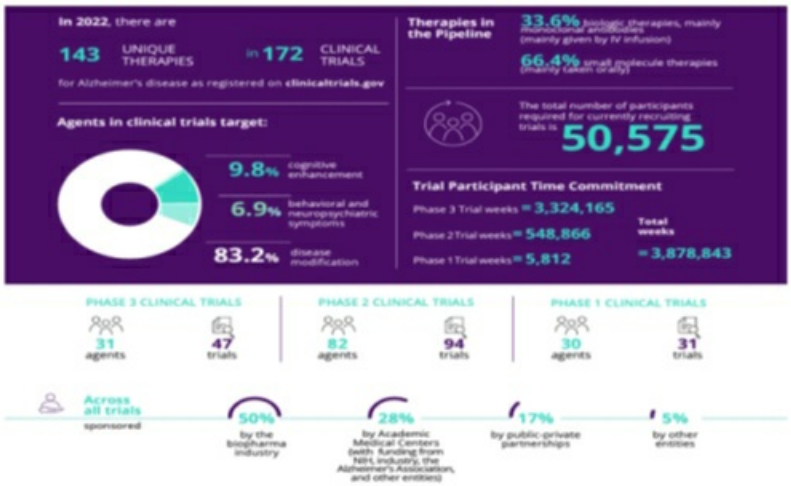
Alzheimer's

Currently, Alzheimer's is the seventh leading cause of death in the U.S. and, when extrapolated globally, the market for preventions, treatments and cures of this crippling disease is massive. Since 1990, life expectancy has increased by six years and the worldwide average continues to increase. With the increase in the mean age of the population in developed countries, the prevalence of deteriorating neurological diseases has also increased. According to the Alzheimer's Association, in the U.S. alone, one of nine persons older than 65 has Alzheimer's, with roughly 6.9 million Americans currently living with it. It is estimated that this number will grow to 13 million by 2050 barring the development of medical breakthroughs to prevent, slow or cure the disease. Many Alzheimer's related associations believe the actual number of adults with Alzheimer's may be much higher since current statistics do not account for deaths from complications or from related diseases like pneumonia or heart attack. These death certificates only list the most immediate cause. The fastest growing age group in the U.S. is the "over 85" group within which one in three individuals has Alzheimer's.

It is estimated that the cost of caring for people with Alzheimer's and other dementias will increase from an estimated $360 billion in 2024 to a projected $1 trillion per year by 2050 with Medicare and Medicaid covering approximately 70% of such costs. Over 11 million Americans provide unpaid care for people with Alzheimer's or other dementias. The Alzheimer's Association estimated that, in 2023, caregivers to individuals with Alzheimer's provided 18.4 billion hours of care valued at $346.6 billion.

Alzheimer's Therapeutic Landscape

According to the Alzheimer's Association, the following is a pictorial representation of the more recent published data encompassing the Alzheimer's therapeutics landscape.



There are currently several experimental therapeutic agents for Alzheimer's in various stages of development with clinical testing directed towards amyloid-beta, or Aβ, clearance, and inhibition of Tau protein aggregation or phosphorylated-Tau, or pTau, clearance. In June 2021, the FDA approved Biogen's Alzheimer's drug aducanumab, also known as Aduhelm, making it the first medication cleared by U.S. regulators to reduce amyloid plaques in people living with Alzheimer's and the first new medication for the disease in nearly two decades. There were previously no drugs cleared by the FDA that can slow the mental decline caused by Alzheimer's, which is the seventh-leading cause of death in the U.S. In July 2023, an anti-beta amyloid antibody known as Lecanemab-irmb ("Leqembi"), received full approval by FDA for treatment of Alzheimer's. In July 2024, the FDA approved Eli Lilly's Alzheimer's drug donanemab, also known as Kisunla, which targets amyloid in the brain. Given the current weight of evidence, amyloid is now established as a cause of Alzheimer's.

Both Leqembi and Kisunla are humanized monoclonal antibodies that bind with high affinity to soluble amyloid-beta oligomers, which reportedly are toxic to neurons. Both Leqembi and Kisunla reduced biomarkers of amyloid in early Alzheimer's and resulted in moderately less decline on measures

of cognition and function compared to placebo at 18 months. Since Leqembi and Kisunla only provide passive immunity, antibody infusions are needed every 2 or 4 weeks, respectively. Both Leqembi and Kisunla support and validate the amyloid theory, but in routine medical practice there will be a large burden on the health care system due to the need for bi-weekly or monthly infusions.

Bipolar Disorder

BD, previously known as manic depression, is a mood disorder characterized by periods of depression and periods of abnormally elevated happiness that each lasts from days to weeks. If the elevated mood is severe or associated with psychosis, it is called mania; if it is less severe, it is called hypomania. During mania, an individual behaves or feels abnormally energetic, happy, or irritable, and they often make impulsive decisions with little regard for the consequences. There is usually also a reduced need for sleep during manic phases. During periods of depression, the individual may experience crying and have a negative outlook on life and poor eye contact with others. The risk of suicide is high; over a period of 20 years, 6% of those with BD died by suicide, while 30–40% engaged in self-harm. Other mental health issues, such as anxiety disorders and substance use disorders, are commonly associated with BD.

While the causes of BD are not clearly understood, both genetic and environmental factors are thought to play a role. Many genes, each with small effects, may contribute to the development of the disorder. Genetic factors account for about 70–90% of the risk of developing BD. Environmental risk factors include a history of childhood abuse and long-term stress. The condition is classified as bipolar I disorder if there has been at least one manic episode, with or without depressive episodes, and as bipolar II disorder if there has been at least one hypomanic episode (but no full manic episodes) and one major depressive episode. If these symptoms are due to drugs or medical problems, they are not diagnosed as BD. Other conditions that have overlapping symptoms with BD include attention deficit hyperactivity disorder, personality disorders, schizophrenia, and substance use disorder as well as many other medical conditions. Medical testing is not required for a diagnosis, though blood tests or medical imaging can rule out other problems.

BD occurs in approximately 1% of the global population. According to the NIH, roughly seven million are estimated to be affected at some point in their lives; rates appear to be similar in females and males. Symptoms most commonly begin between the ages of 20 and 25 years old; an earlier onset in life is associated with a worse prognosis. Interest in functioning in the assessment of patients with BD is growing, with an emphasis on specific domains such as work, education, social life, family, and cognition. Around one-quarter to one-third of people with BD have financial, social or work-related problems due to the illness. BD is among the top 20 causes of disability worldwide and leads to substantial costs for society. Due to lifestyle choices and the side effects of medications, the risk of death from natural causes such as coronary heart disease in people with BD is twice that of the general population.

Bipolar Disorder Therapeutic Landscape

Mood stabilizers, including lithium and certain anticonvulsants, such as valproate and carbamazepine, as well as atypical antipsychotics, such as aripiprazole, are the mainstay of long-term pharmacologic relapse prevention. Antipsychotics are additionally given during acute manic episodes as well as in cases where mood stabilizers are poorly tolerated or ineffective. In patients where compliance is of concern, long-acting injectable formulations are available. There is some evidence that psychotherapy improves the course of BD. The use of antidepressants in depressive episodes is controversial; they can be effective but have been implicated in triggering manic episodes. The treatment of depressive episodes, therefore, is often difficult. Electroconvulsive therapy (“ECT”) is effective in acute manic and depressive episodes, especially with psychosis or catatonia. Admission to a psychiatric hospital may be required if a person is a risk to themselves or others; involuntary treatment is sometimes necessary if the affected person refuses treatment.

Major Depressive Disorder

MDD, also known simply as depression, is a mental disorder characterized by at least two weeks of pervasive low mood, low self-esteem, and loss of interest or pleasure in normally enjoyable activities. Those affected may also occasionally have delusions or hallucinations. Introduced by a group of U.S. clinicians in the mid-1970s, the term was adopted by the American Psychiatric Association for this symptom cluster under mood disorders in the 1980 version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-III) and has become widely used since.

The diagnosis of MDD is based on the person's reported experiences and a mental status examination. There is no laboratory test for the disorder, but testing may be done to rule out physical conditions that can cause similar symptoms. The most common time of onset is in a person’s 20s, with females affected about twice as often as males. The course of the disorder varies widely, from one-episode lasting months to a lifelong disorder with recurrent major depressive episodes.

MDD is believed to be caused by a combination of genetic, environmental, and psychological factors, with about 40% of the risk being genetic. Risk factors include a family history of the condition, major life changes, certain medications, chronic health problems, and substance use disorders. It can negatively affect a person's personal life, work life, or education as well as sleeping, eating habits, and general health. According to the NIH, MDD affected approximately 21 million adults (8.4% of all U.S. adults) in 2020. The prevalence of adults with a major depressive episode was higher among adult females (10.5%) than males (6.2%). The prevalence of adults with a major depressive episode was highest among individuals aged 18-25 (17.0%). MDD causes the second-most years lived with disability, after lower back pain.

Major Depressive Therapeutic Landscape

Those with MDD are typically treated with psychotherapy and antidepressant medication. Medication appears to be effective, but the effect may predominantly be significant in the most severely depressed. Hospitalization (which may be involuntary) may be necessary in cases with associated self-neglect or a significant risk of harm to self or others. ECT may be considered if other measures are not effective.

Although lithium does not have an FDA approved indication for augmentation of an antidepressant in MDD, it has been prescribed off-label for this purpose for decades. While a wide variety of medications have been used historically in this capacity, lithium is one of the few agents that has demonstrated efficacy in multiple randomized controlled trials. Although the ideal role for lithium augmentation has yet to be established, there is evidence to support the clinical practice of adding lithium to conventional antidepressants in pursuit of MDD remission. Lithium augmentation has been cited as a main strategy for depressed patients not responding to an antidepressant, lithium prophylaxis for recurrent unipolar depression as an alternative to prophylaxis with an antidepressant, and for lithium's anti-suicidal properties, where appropriate.

Post-Traumatic Stress Disorder

PTSD is a mental and behavioral disorder that can develop because of exposure to a traumatic event, such as sexual assault, warfare, traffic

collisions, child abuse, domestic violence, or other threats to a person's life. Symptoms may include disturbing thoughts, feelings, or dreams related to the events, mental or physical distress to trauma-related cues, attempts to avoid trauma-related cues, alterations in the way a person thinks and feels, and an increase in the fight-or-flight response. These symptoms may remain for more than a month after the event. A person with PTSD is at a higher risk of suicide and intentional self-harm.

Most people who experience traumatic events do not develop PTSD. People who experience interpersonal violence such as rape, other sexual assaults, being kidnapped, stalking, physical abuse by an intimate partner, and incest or other forms of childhood sexual abuse are more likely to develop PTSD than those who experience non-assault-based trauma, such as accidents and natural disasters. Those who experience prolonged trauma, such as slavery, concentration camps, or chronic domestic abuse, may develop complex post-traumatic stress disorder ("C-PTSD"). C-PTSD is similar to PTSD but has a distinct effect on a person's emotional regulation and core identity.

According to the NIH, about 3.5%, or roughly nine million, adults in the U.S. have PTSD in a given year, and 9% of people develop it at some point in their life. In much of the rest of the world, rates for a given year are between 0.5% and 1% of the population. Higher rates may occur in regions of armed conflict. It is more common in women than men. PTSD was first mentioned in the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (DSM-I) in the 1950s under the term "gross stress reaction." Although this diagnosis included psychological problems related to traumatic events such as wartime combat, it limited symptoms to six months. This diagnosis was removed from the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (DSM-II) in 1968, representing a regression in accurate PTSD characterization. The long-term psychological disabilities experienced by trauma survivors, including Vietnam veterans, sexual assault victims and Holocaust survivors led to the introduction of PTSD in the American Psychiatric Association Diagnostic and Statistical Manual of Mental Disorders (DSM-III) in 1980, where, for the first time, the definition of PTSD highlighted the critical connection between traumatic events and long-term psychological symptoms.

Post-Traumatic Stress Disorder Therapeutic Landscape

Prevention may be possible when counselling is targeted at those with early symptoms but is not effective when provided to all trauma-exposed individuals, whether or not symptoms are present. The main treatments for people with PTSD are counselling (psychotherapy) and medication. Antidepressants of the selective serotonin reuptake inhibitors ("SSRI") or serotonin-norepinephrine reuptake inhibitors ("SNRI") type are the first-line medications used for PTSD and are moderately beneficial for about half of people. Benefits from medication are less than those seen with counselling. It is not known whether using medications and counselling together has greater benefit than either method separately.

Sertraline (Zoloft) and Paroxetine (Paxil) are FDA-approved medications for PTSD. Reviews by a group of doctors of pharmacological monotherapy in 2015 and 2021 found that paroxetine, fluoxetine, sertraline and venlafaxine could be effective for PTSD, but the magnitude of the effect was low and the clinical relevance was unclear. These reviews excluded lithium treatments. Medications, other than some SSRIs or SNRIs, do not have enough evidence to support their use and, in the case of benzodiazepines, may worsen outcomes.

Case reports suggest that lithium treatment may be useful for irritability/anger outbursts in PTSD patients. For example, one study by Kitchner and Greenstein provided case histories of four males (aged approximately 31–42 years) who suffered from PTSD resulting from their experiences in the Vietnam War. Results from treatment with low doses (300–600 mg/day) of lithium carbonate were reported to indicate that treatment was effective in reducing inappropriate anger, irritability, anxiety, and insomnia.

The clinical observation of mood swings beyond the normal range but milder than those associated with BD reportedly suggested the presence of a subthreshold mood disorder in these PTSD patients. It has also been proposed that treatment of trauma with lithium to forestall the development of PTSD may be provided by pharmacological induction of a mild transient amnesia.

Manufacturing

Currently, we do not have in-house manufacturing capabilities. We have outsourced and expect to continue to outsource the manufacturing of our products to third party contractors with special capabilities to manufacture chemical drugs and biologic drug candidates for submission and clinical testing under FDA guidelines and, for AL001 and ALZN002, have received Good Manufacturing Practices, or GMP, material manufactured for clinical trial. There are several sources of manufacturing available once a therapy or treatment can achieve Phase II study as identified in a publication by Pharma.org released in 2013 (http://www.phrma.org/sites/default/files/Alzheimer's%202013.pdf).

Distribution and Marketing

We intend to develop AL001 and ALZN002 through successive de-risking milestones towards regulatory approval and seek marketing approval of AL001 and ALZN002 or enter into partnering transactions with biopharmaceutical companies seeking to strategically fortify pipelines and, in turn, receiving funding for the costly later-stage clinical development required to achieve successful commercialization. We do not anticipate selling products directly into the marketplace, though we may do so depending on market conditions. Our focus is to strategically effect partnering transactions that will provide distribution and marketing capabilities to sell products into the marketplace.

Government Regulation

Clinical trials, the pharmaceutical approval process, and the marketing of pharmaceutical products, are intensively regulated in the United States and in all major foreign countries.

Human Health Product Regulation in the United States

In the United States, the FDA regulates pharmaceuticals under the Federal Food, Drug, and Cosmetic Act and related regulations promulgated thereunder. Pharmaceuticals are also subject to other federal, state, and local statutes and regulations. Failure to comply with applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA of an Institutional Review Board, or IRB, a clinical hold on trials, a refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or referrals to the Department of Justice for criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions impose substantial requirements upon the clinical development, manufacturing and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our products.

The FDA's policies may change, and additional government regulations may be promulgated that could prevent or delay regulatory approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or elsewhere.

Marketing Approval

The process required by the FDA before human health care pharmaceuticals may be marketed in the U.S. generally involves the following:

- nonclinical laboratory and, at times, animal tests;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of an NDA or BLA, which must occur before a drug or biologic product can be marketed or sold.

We will need to successfully complete sufficient clinical trials in order to be in a position to submit a BLA or NDA to the FDA. We must reach agreement with the FDA on the proposed protocols for our future clinical trials in the U.S. A separate submission to the FDA must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site, and an informed consent must also be obtained from each study subject. Regulatory authorities, a data safety monitoring board or the sponsor may all suspend or terminate a clinical trial at any time on numerous grounds.

For purposes of BLA or NDA approval for human health products, human clinical trials are typically conducted in phases that may overlap.

- Phase I. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase II. This phase involves trials in a limited subject population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase II studies may be sub-categorized into Phase IIA studies which are smaller, pilot studies to evaluate limited drug exposure and efficacy signals, and Phase IIB studies, which are larger studies testing both safety and efficacy more rigorously.
- Phase III. This phase involves trials undertaken to further evaluate dosage, clinical efficacy and safety in an expanded subject population, often at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

All of these trials must be conducted in accordance with Good Clinical Practice (“GCP”), requirements in order for the data to be considered reliable for regulatory purposes.

New Drug and Biologics License Applications

In order to obtain approval to market a pharmaceutical in the United States, a marketing application must be submitted to the FDA that provides data establishing to the FDA’s satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA or BLA submission requires a substantial user fee payment unless a waiver or exemption applies (such as with the Orphan Drug Designation discussed below). For fiscal year 2023, the FDA set the application fee at $3,242,026 for new drug applications that require clinical data. The manufacturer and/or sponsor of certain drugs approved under an NDA or BLA is also subject to annual prescription drug program fees, currently set at $393,933 per product for fiscal year 2023. These fees are typically increased annually. The NDA or BLA includes all relevant data available from pertinent non-clinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product’s chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of the use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the NDA or BLA for completeness before it accepts it for filing. The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency’s threshold determination that the application is sufficiently complete to permit substantive review. After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with current GMP, or cGMP, to assure and preserve the product’s identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it typically considers such recommendations carefully when making decisions.

Based on pivotal Phase III trial results submitted in an NDA or BLA, upon the request of an applicant, the FDA may grant a “Priority Review” designation to a product, which sets the target date for FDA action on the application at six to eight months, rather than the standard ten to 12 months. The FDA can extend these reviews by three months. Priority Review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a significant improvement compared to marketed products or offers a therapy where no satisfactory alternative therapy exists. Priority Review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

After the FDA completes its initial review of an NDA or BLA, it will communicate to the sponsor that the application for the drug will either be approved, or it will issue a complete response letter to communicate that the NDA or BLA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, nonclinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured, even if such facilities are located overseas. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and are adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical sites and manufacturing sites to assure compliance with GCP and GMP. If the FDA determines that any of the application, manufacturing process or manufacturing facilities is not acceptable, it typically will

outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine that the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA or BLA. Additionally, the FDA may identify deficiencies in the manufacturing process and require changes prior to approval. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a drug requires substantial time, effort and financial resources, and this process may take several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

The FDA may require, or companies may at their own discretion pursue, additional clinical trials after a product is approved. These so-called Phase IV studies may be made a condition that must be satisfied for continuing drug approval. The results of Phase IV studies can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency. Any approvals that we may ultimately receive could be withdrawn if required post-marketing trials or analyses do not meet the FDA requirements, which would materially harm the commercial prospects for AL001 or ALZN002.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (“REMS”), from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA or BLA submission. The need for a REMS is determined as part of the review of the NDA or BLA. Based on statutory standards, elements of a REMS may include “dear doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the NDA or BLA approval, and in some cases if consensus is not obtained until after the Prescription Drug User Fee Act review cycle, the approval date may be delayed. Once adopted, a REMS is subject to periodic assessment and modification.

Even if AL001 or ALZN002 receives regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Any delay in obtaining, or failure to obtain, regulatory approval for AL001 or ALZN002, or obtaining approval only for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

Breakthrough Therapy Designation

A product can be designated as a breakthrough therapy if it is intended to treat a serious condition (which includes Alzheimer’s) and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). For purposes of breakthrough therapy designation, a clinically significant endpoint generally refers to an endpoint that measures an effect on irreversible morbidity or mortality (“IMM”), or on symptoms that represent serious consequences of the disease. A clinically significant endpoint can also refer to findings that suggest an effect on IMM or serious symptoms, including:

- an effect on an established surrogate endpoint;
- an effect on a surrogate endpoint or intermediate clinical endpoint considered reasonably likely to predict a clinical benefit (i.e., the accelerated approval standard);
- an effect on a pharmacodynamic biomarker (which is a measurable indicator of the disease state) that does not meet criteria for an acceptable surrogate endpoint, but strongly suggests the potential for a clinically meaningful effect on the underlying disease; and

- a significantly improved safety profile compared to available therapy (e.g., less dose-limiting toxicity for an oncology agent), with evidence of similar efficacy.

A drug that receives a breakthrough therapy designation is eligible for fast-track designation features, intensive guidance on an efficient drug development program and FDA organizational commitment involving senior managers. However, we have not yet applied for breakthrough therapy designation nor have we received any official designation for expedited development. Our product candidates may not qualify for breakthrough therapy designation; further, even if it does qualify for breakthrough therapy designation, it may not actually lead to faster development or expedited regulatory review and approval or necessarily increase the likelihood that it will receive FDA approval.

Based on our preclinical data, AL001 has a positive effect on the pharmacodynamic biomarkers of Alzheimer’s. We intend to validate this clinically and if confirmed, we believe that AL001 is a candidate for breakthrough therapy designation because of its positive effect on a pharmacodynamic biomarker (beta-amyloids) and potential for a clinically meaningful effect on Alzheimer’s. We also believe that ALZN002 is positioned for a breakthrough therapy designation because of its positive effect on a pharmacodynamic biomarker (beta-amyloids) and potential for a clinically meaningful effect on Alzheimer’s.

Section 505(b)(2) New Drug Applications

Companies may also consider seeking FDA approval through the Section 505(b)(2) NDA process if their product candidates are similar to previously approved drugs but differ in dosage form, strength, route of administration, formulation or indication. Section 505(b)(2) of the Food, Drug, and Cosmetic Act was enacted as part of the Drug Price Competition and Patent Term Restoration Act of 1984 and is also known as the Hatch-Waxman Amendments. The purpose of Section 505(b)(2) is to allow companies to avoid duplicative testing by allowing applicants to utilize data from previous clinical and non-clinical studies in the current NDA submission, when pertinent. The 505(b)(2) application process requires, among other things, the submission of data from studies demonstrating the product’s safety and efficacy for the new indication.

We believe that AL001 is positioned for an expedited Section 505(b)(2) regulatory pathway for a new drug. AL001’s active pharmaceutical ingredients (lithium, proline and salicylate) are well documented and approved by the FDA. The provisions of 505(b)(2) were created, in part, to help avoid unnecessary duplication of studies already performed on a previously approved (“reference” or “listed”) drug. This section gives the FDA express permission to rely on data not developed by the NDA applicant. This process can result in a much less expensive and much faster route to approval, compared with a traditional development path such as 505(b)(1), while creating new, differentiated products with tremendous commercial value.

The Hatch-Waxman Amendments permit companies to rely upon not only certain published nonclinical or clinical studies conducted for an approved product, but also the FDA’s conclusions from a prior review of the studies. Additionally, the FDA may require companies to perform further studies to support changes from the approved product. After completion of the review, the FDA may approve the new product for all or some of the labeled indications for which the reference product has been approved, as well as for any new indication supported by the NDA. While references to

nonclinical and clinical data not created by the applicant or for which the applicant does not have a right of reference are allowed, the applicant must still submit data related to the manufacturing and quality of the product candidate, such as information about the development, process, stability, qualification and validation.

If a company chooses to rely on the FDA's conclusions regarding studies conducted for an already approved product, the company is required to provide a certification statement for any patents listed for the approved product in the FDA's Orange Book publication. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The FDA will also not approve a Section 505(b)(2) until any non-patent exclusivity period for the reference product has expired, such as the exclusivity granted for obtaining approval of a new chemical entity.

If we qualify for the Section 505(b)(2) regulatory pathway for new drug approvals, we believe we can shorten the development timeline for AL001. However, our AL001 may not qualify for expedited development or, if it does qualify for expedited development, it may not actually lead to faster development or expedited regulatory review and approval.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the NIH. Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly available information to gain knowledge regarding the design and progress of our development programs.

The Drug Price Competition and Patent Term Restoration Act

The Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, requires pharmaceutical companies to divulge certain information regarding their products, which has the effect of making it easier for other companies to manufacture generic drugs to compete with those products.

Patent Term Extension. After receipt of an NDA or BLA approval, owners of relevant drug patents may apply for a patent extension of up to five years. The permissible patent term extension is calculated as half of the drug's testing phase, that is, the time between IND submission and NDA or BLA submission, and all of the review phase, or the time between either NDA or BLA submission and approval up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the U.S. Patent and Trademark Office, or USPTO, must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA or BLA has not been submitted.

Environmental Regulations. The U.S. generally requires an environmental assessment, which discusses a company's proposed action, possible alternatives to the action, and whether the further analysis of an environmental impact statement is necessary. Certain exemptions are available from the requirement to perform an environmental assessment and an environmental impact statement. Once an exemption is claimed, a company must state to the FDA that no extraordinary circumstances exist that may significantly affect the environment. We may claim an exemption, under the category for biologic products, from the requirement to provide an environmental assessment and an environmental impact statement for AL001 or ALZN002 and further state to the FDA that, to our knowledge, no extraordinary circumstance exists that would significantly affect the environment.

FDA Post-Approval Requirements

Following the approval of an NDA or BLA, the FDA continues to require adverse event reporting and submission of periodic reports. The FDA also may require post-marketing testing, known as Phase IV testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a manufacturer fails to comply with regulatory standards, if it encounters problems following initial marketing or if previously unrecognized problems are subsequently discovered.

Patient Protection and Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act, or the ACA, which includes measures that have significantly changed the way health care is financed by both governmental and private insurers, became law in the U.S. The ACA is a sweeping measure intended to expand health care coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The ACA has significantly impacted the pharmaceutical industry. The ACA requires discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the ACA imposes an annual fee, which increases annually, on sales by branded pharmaceutical manufacturers. At this time, the financial impact of these discounts, increased rebates and fees and the other provisions of the ACA on our business are unclear. However, the fees, discounts and other provisions of this law are expected to have a significant negative effect on the profitability of pharmaceuticals.

Human Health Product Regulation in the European Union

In addition to domestic regulations, we may eventually be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a process that requires the submission of a clinical trial application prior to the commencement of human clinical trials. In Europe, for example, a Clinical Trial Application ("CTA") must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country's requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the EU Member States resulting from the national implementation of underlying EU legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under European Union regulatory systems, we will be required to submit a marketing authorization application. This application is similar to the BLA in the United States, with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the European Union by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) the national authorization procedure.

The European Medicines Agency ("EMA") implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization granted by the European Commission that is valid across the EU, as well as in Iceland, Liechtenstein and Norway, at times referred to as the European Economic Area. The centralized procedure is compulsory for human drugs that: (i) are derived from biotechnology processes, such as genetic engineering; (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases; (iii) are officially designated orphan drugs; and (iv) constitute advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs that do not fall within the above mentioned categories if the human drug (a) contains a new active substance which, on the date of entry into force of Regulation (EC) No. 726/2004, was not authorized in the European Economic Area; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients at European Economic Area level.

Under the centralized procedure in the European Union, the maximum timeframe for the evaluation of a Marketing Authorization Application by the EMA is 210 days, though the date count stops whenever the Committee for Medicinal Products for Human Use ("CHMP") asks the applicant for additional written or oral information, with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, as when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: (i) the seriousness of the disease to be treated; (ii) the absence of an appropriate alternative therapeutic approach; and (iii) anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter.

The Mutual Recognition Procedure ("MRP") for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the European Union. Essentially, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products and is based on the principle of recognition of an already existing national marketing authorization by one or more EU Member States.

The principal characteristic of the MRP is that the procedure builds on an already existing marketing authorization in an EU Member State that is used as reference in order to obtain marketing authorizations in other Member States. In the MRP, a marketing authorization for a drug already exists in one or more EU Member States and subsequently marketing authorization applications are made in other EU Member States by referring to the initial marketing authorization. The EU Member State in which the marketing authorization was first granted will then act as the referenced EU Member State. The EU Member States where the marketing authorization is subsequently applied for act as concerned EU Member States.

The MRP is based on the principle of mutual recognition by EU Member States of their respective national marketing authorizations. Based on a marketing authorization in the reference EU Member State, the applicant may apply for marketing authorizations in other EU Member States. In such case, the reference EU Member State will update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all EU Member States, together with the approved summary of product characteristics, labeling and package leaflet. The concerned EU Member States then have 90 days to recognize the decision of the referenced EU Member State and the summary of product characteristics, labeling and package leaflet. National marketing authorizations will be granted within 30 days after acknowledgement of the agreement.

If any EU Member State refuses to recognize the marketing authorization by the reference EU Member State on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within 60 days, EU Member States will, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products.

Human Health Product Regulation in the Rest of World

For countries outside of the EU, such as the United Kingdom, Canada, countries in Eastern Europe or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

Other Regulatory Considerations

Labeling, Marketing and Promotion. Once an NDA or BLA is approved, or just before approval, a product will be subject to certain marketing and promotional requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of pharmaceuticals, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities on the internet and elsewhere.

While appropriate medical professionals are free to prescribe any pharmaceutical approved by the FDA for any use, a company can only make claims relating to the safety and efficacy of a pharmaceutical that are consistent with the FDA approval, and is only allowed to actively market a pharmaceutical for the particular indication approved by the FDA. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA/BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing NDAs.

In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties. Government regulators recently have increased their scrutiny of the promotion and marketing of pharmaceuticals.

Anti-Kickback and False Claims Laws. In the United States, we are subject to complex laws and regulations pertaining to health care "fraud and abuse," including, but not limited to, the federal Anti-Kickback Statute, the federal False Claims Act, state false claims acts and anti-kickback statutes, and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular pharmaceutical, for which payment may be made under a federal health care program, such as Medicare or Medicaid.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including pharmaceuticals, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

Many states have similar anti-kickback or false claims statutes that can be even broader than their federal counterparts. There is also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, a federal law known as the Physician Payments Sunshine Act requires pharmaceutical manufacturers to track and report to the federal government certain payments and other transfers of value made to physicians and teaching hospitals and to disclose any physician ownership in the previous calendar year. The data is published annually in a publicly searchable database. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

Other Health Care Laws and Compliance Requirements. In the United States, our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the U.S. Department of Health and Human Services (e.g., its Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/ educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992, or VHCA, each as amended, among others. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements will apply. Under the VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including U.S. Department of Veteran Affairs and U.S. Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Legislative changes also require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors that ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities or register their sales representatives. Other legislation has been enacted in certain states prohibiting pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing and prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection, unfair competition and other laws and regulations.

Our Intellectual Property

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret or is protected by confidentiality agreements. Accordingly, patents or other proprietary rights are an essential element of our business. Currently, we do not own a patent, although we do possess a license for an immunotherapy technology and three licenses for a lithium, salicylate and proline cocrystal technology from the Licensor.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depending on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

A summary of the licensed patents is as follows:

Title of Patent	Patent Type	Therapeutic Drug	Date Filed	Date Issued	Expiration Date	Patent #
Lithium Cocrystals and an Additional Neuropsychiatric Agent for Treatment of Neuropsychiatric Disorders	Method of Use	AL001 (LISPRO)	05/21/2016	03/28/2017	05/21/2036	9,603,869
Organic Anion Lithium Ionic Cocrystal Compounds and Compositions	Composition of Matter	AL001 (LISPRO)	04/18/2014	12/12/2017	04/18/2034	9,840,521
Amyloid Beta Peptides and Methods of Use	Composition of Matter	ALZN002 (E22W)	10/12/2007	05/29/2012	02/12/2028	8,188,046

While trade secret protection is an essential element of our business and we take security measures to protect our proprietary information and trade secrets, there can be no assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that our employees, consultants or any third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we take to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict

whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or ourselves, we may face costly litigation and the diversion of our management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

We currently have four trademarks registered with the USPTO that include our corporate name, Alzamend Neuro, two for our corporate slogan and one for our trade name.

Our Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we have some, albeit limited, development experience and scientific knowledge, we will face competition from both large and small pharmaceutical and biotechnology companies, including specialty pharmaceutical companies and generic drug companies, as well as academic institutions, government agencies and research institutions, among others.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. It is likely that the timing of market introductions of some of our potential products or our competitors' products will be an important competitive factor. Accordingly, the speed with which we can develop our products, conduct preclinical studies and clinical trials to obtain approval and manufacture or obtain supplies of commercial quantities of any approved products should also be important competitive factors. We expect that competition among products approved for sale will be based on additional factors such as product efficacy, safety, reliability, availability, price and patent position.

Employees and Human Capital Resources

As of April 30, 2024, we have four full-time employees and three part-time employees. We also utilize independent consultants to assist us in our medical research and development projects.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

ITEM 1A. RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Annual Report, including our financial statements and the related notes and the section of this Annual Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to Our Company, Early Stage of Clinical Development and Financial Condition

We need to obtain substantial additional funding to complete the development and any commercialization of AL001 and ALZN002. If we are unable to raise this capital when needed, we may be forced to delay, reduce or eliminate our research and development programs and other operations.

We expect our expenses to increase substantially during the next few years. The development of biotechnology product candidates is capital intensive. As we conduct non-clinical research and clinical development of our product candidates, we will need substantial additional funds to maintain and expand our capabilities in a variety of areas including discovery and non-clinical research, clinical development, regulatory affairs, product development, product quality assurance, and pharmacovigilance. In addition, if we obtain marketing approval for any of our product candidates, we expect to incur significant commercialization expenses for marketing, sales, manufacturing and distribution. Some of those commercialization investments may be made at-risk in advance of receiving an approval.

As of April 30, 2024, we had $376,000 in cash and cash equivalents. In May 2024, subsequent to the end of our fiscal year, we entered into a transaction with an investor that, if the investor bides by its commitments, should produce a temporarily significant dollar amount of financing, subject to our ability to achieve certain milestones. Based on our current operating plan, we believe that this funding will be enable us to fund our operations for the next twelve months. In particular, we need additional funds to allow us to fund Phase II clinical trials for AL001 in Alzheimer's, BD, MDD and PTSD and to complete the on-going Phase I/IIA clinical trial for ALZN002 to treat mild to moderate dementia of the Alzheimer's type. However, changing circumstances or inaccurate estimates by us may cause us to use capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. For example, our ongoing clinical trial for ALZN002 or our planned clinical trials for AL001 may encounter technical, enrollment or other issues that could cause our development costs to increase more than we expect. We will not have sufficient funds to complete any of these planned or ongoing clinical trials or the clinical development of either AL001 or ALZN002 through regulatory approval. We will need to raise substantial additional capital to complete the development and commercialization of each of those product candidates, which additional capital, if available on reasonable terms if at all, may be raised through the sale of our common stock or other securities or through the entering into of alternative strategic transactions, or cause our stockholders to incur substantial dilution.

Our future capital requirements will depend on many factors, including:

- the initiation, progress, timing, costs and results of our planned clinical trials for our product candidates;
- the number and scope of indications we decide to pursue for product development;
- the cost, timing and outcome of regulatory review of any NDA or BLA we may submit for our product candidates;
- the costs and timing of manufacturing for our product candidates, if approved;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;

- our efforts to enhance operational systems and our ability to attract, hire and retain qualified personnel, including personnel to support the development of our product candidates;

- the costs associated with being a public company;

- our ability to enter into partnerships or otherwise monetize our pipeline through strategic transactions on a timely basis, on terms that are favorable to us, or at all;

- the terms and timing of establishing and maintaining collaborations, licenses and other similar arrangements;

- the extent to which we acquire or in-license other product candidates and technologies; and

- the cost associated with commercializing our product candidates, if any are approved for commercial sale.

Our commercial revenues, if any, will be derived from sales of products that we do not expect to be commercially available for sale for at least the next several years, if ever. Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. Adequate additional financing may not be available to us on acceptable terms, or at all. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate our research and development programs or other operations.

Our independent registered public accounting firm has expressed substantial doubt about our ability to continue as a going concern.

Our independent registered public accounting firm has issued a going concern opinion on our financial statements for the year ended April 30, 2024, expressing substantial doubt that we can continue as an ongoing business due to insufficient capital for us to fund our operations. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to successfully raise additional capital, we will need to create and implement alternate operational plans to continue as a going concern, and investors or other financing sources may be unwilling to provide additional funding to us on commercially reasonable terms or at all.

We are at an early stage of clinical development and currently have no source of near-term revenue and may never become profitable.

We are a clinical-stage biopharmaceutical company. We have recently initiated clinical trials for our AL001 and ALZN002 programs. To date, we have not initiated or completed a pivotal clinical trial, obtained marketing approval for any product candidates, manufactured a commercial scale product or arranged for a third party to do so on our behalf, or conducted sales and marketing activities necessary for successful product commercialization. Our ability to generate revenue depends heavily on, among other developments:

- demonstration to the satisfaction of the FDA and comparable regulatory bodies that AL001 and ALZN002 are safe and effective in future clinical trials;

- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;

- if approved by the FDA, successful manufacture and commercialization of AL001 and ALZN002; and

- market acceptance of AL001 and ALZN002.

We only have two product candidates, AL001 and ALZN002, which will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before either or both of them, and any respective successors, will provide us with any revenue. As a result, if we do not successfully develop, achieve regulatory approval for and commercialize AL001 or ALZN002, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for a few years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

We have a limited operating history on which to judge our business prospects and management.

We were incorporated in February 2016 and commenced operations shortly thereafter. We have a limited operating history upon which to base an evaluation of our business and prospects. Operating results for future periods are subject to numerous uncertainties and we cannot assure you that we will achieve or sustain profitability. Our prospects must be considered in light of the risks encountered by companies in the early stage of development, particularly companies in new and rapidly evolving markets. Future operating results will depend upon many factors, including our success in attracting and retaining motivated and qualified personnel, our ability to establish short term credit lines or obtain financing from other sources, our ability to develop and market new products or control costs, and general economic conditions. We cannot assure you that we will successfully address any of these contingencies.

Risks Related to Our Product Candidates

We have both operational and financial milestones that must be met to maintain the licensing rights to our current technology and intellectual property from the Licensor.

There are certain license fees and milestone payments required to be paid by us to the Licensor, pursuant to the terms of license agreements we have entered into with the Licensor. The license agreements for ALZN002 require us to pay royalty payments of 4% on net sales of products developed from the licensed technology for ALZN002 while the license agreements for AL001 require that we pay combined royalty payments of 4.5% on net sales of products developed from the licensed technology for AL001. We have already paid an initial license fee of $200,000 for ALZN002 and an initial license fee of $200,000 for AL001. As an additional licensing fee for the license of ALZN002, the Licensor received 24,012 shares of our common stock. As an additional licensing fee for the license of the AL001 technologies, the Licensor received 14,853 shares of our common stock. Minimum royalties for AL001 License Agreements are $40,000 on the first anniversary of the first commercial sale, $80,000 on the second anniversary first commercial sale and

$100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the AL001 License Agreements. Minimum royalties for ALZN002 are $20,000 on the first anniversary of the first commercial sale, $40,000 on the second anniversary first commercial sale and $50,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the ALZN002 License Agreement. Minimum royalties for November AL001 License Agreements are $40,000 on the first anniversary of the first commercial sale, $80,000 on the second anniversary first commercial sale and $100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the November AL001 License Agreements .Additionally, we are required to pay milestone payments on the due dates to the Licensor for the license of the AL001 technologies and for the ALZN002 technology, as follows:

Original AL001 Licenses:

Payment	Due Date	Event
$ 50,000*	Completed September 2019	Pre-IND meeting
$ 65,000*	Completed June 2021	IND application filing
$ 190,000*	Completed December 2021	Upon first dosing of patient in a clinical trial
$ 500,000*	Completed March 2022	Upon Completion of first clinical trial
$ 1,250,000	March 2025	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	8 years from the effective date of the agreement	Upon FDA NDA approval

*Milestone met and completed

If we fail to meet a milestone payment by the specified date, the Licensor may terminate the respective license agreement. If the Licensor were to terminate either license agreement for whatever reason, it would materially and adversely affect our business, financial position and future prospects and you would likely lose the entirety of your investment in us.

ALZN002 License:

Payment	Due Date
$ 50,000*	Completed January 2022
$ 50,000	Upon first dosing of patient in first Phase I clinical trial
$ 500,000	Upon completion of first Phase IIB clinical trial
$ 1,000,000	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	Upon first commercial sale

*Milestone met and completed

Additional AL001 Licenses:

Payment	Due Date	Event
$ 2,000,000	March 2026	Upon first patient treated in a Phase III clinical trial
$ 16,000,000	August 1, 2029	First commercial sale

These AL001 License Agreements have an indefinite term that continue until the later of the date no licensed patent under the applicable agreement remains a pending application or enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, or the date on which the licensee's obligations to pay royalties expire under the applicable license agreement.

If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with the Licensor, we could lose license rights that are important to our business.

We are a party to these license agreements with the Licensor and expect to enter into additional license agreements in the future. The existing license agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the Licensor, we may lose the exclusivity of our license, or the Licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. The Licensor or any future licensor may take any of these actions, including terminating a license agreement. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates. If the Licensor were to terminate a license agreement for whatever reason, it would materially and adversely affect our business, financial position and future prospects and you would likely lose the entirety of your investment in us.

In some cases, patent prosecution of our licensed technology is controlled solely by the Licensor. If the Licensor fails to obtain and maintain patent or other protection for the proprietary intellectual property we license, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. Licensing of intellectual property is of critical importance to our business and involves complex legal, business and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the Licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under each of the license agreements and what activities satisfy those diligence obligations;

- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and

- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

We are substantially dependent on the success of our product candidates, which may not receive regulatory approval or be successfully commercialized.

In the future, we plan to submit AL001 and ALZN002 and, potentially, other product candidates for regulatory approval. Currently, however, neither AL001 nor ALZN002 has been submitted for regulatory approval, which would be required before we seek to initiate commercial distribution. To date, we have invested nearly all of our resources in establishing our company, acquiring the intellectual property of our product candidates, AL001 and ALZN002 and conducting certain preclinical studies and clinical trials. Our near-term prospects, including our ability to finance our company and to enter into strategic collaborations and, ultimately, to generate revenue, are directly dependent upon the successful development, FDA approval and commercialization of AL001 or ALZN002.

The development and commercial success of our product will depend on a number of factors, including, without limitation, the following:

- our timely initiation and successful completion of preclinical studies and clinical trials for AL001 or ALZN002;

- our demonstration to the satisfaction of the FDA and comparable regulatory bodies of the safety and efficacy of AL001 or ALZN002, as well as to obtain regulatory and marketing approval for AL001 or ALZN002 in the United States, Europe, the United Kingdom and elsewhere;

- our continued compliance with all clinical and regulatory requirements applicable to AL001 and ALZN002;

- our maintenance of an acceptable safety profile of AL001 and ALZN002 following regulatory approval;

- competition with other treatments;

- our creation, maintenance and protection of our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for AL001 and ALZN002;

- the effectiveness of our and our eventual partners' marketing, sales and distribution strategy and operations;

- the ability of our third-party manufacturers to manufacture supplies of our product and product candidates and to develop, validate and maintain commercially viable manufacturing processes;

- our ability to launch commercial sales of AL001 or ALZN002 following regulatory approval, whether alone or in collaboration with others; and

- the acceptance of AL001 and ALZN002 by physicians, health care payers, patients and the medical community.

Many of these factors are beyond our control, and we cannot assure you that we will ever be able to generate sufficient revenue, or any revenue at all, from the sale of AL001 or ALZN002. Our failure in any of the above factors, or in successfully commercializing AL001 or ALZN002 on a timely basis, could have a material adverse effect on our business, results of operations and financial condition, and the value of your investment could substantially decline.

AL001 and ALZN002 may not achieve market acceptance, which would significantly limit our ability to generate revenue.

Even if we develop AL001 or ALZN002 and gain regulatory approvals for either or both candidates, unless physicians and patients accept our product candidates, we may not be able to sell them, whether directly or indirectly, and generate significant revenues. We cannot assure you that AL001, ALZN002 or any other potential product candidates we may eventually develop will achieve market acceptance and revenue if and when they obtain the requisite regulatory approvals. Market acceptance of any product candidate depends on a number of factors, including but not limited to:

- the indication and warnings approved by regulatory authorities in the product label;

- continued demonstration to the FDA of safety and efficacy in commercial use;

- physicians' willingness to prescribe the product;

- reimbursement from third-party payers such as government health care systems and insurance companies;

- the price of the product;

- the nature of any post-approval risk management plans mandated by regulatory authorities;

- competition; and

- the effectiveness of marketing and distribution support.

Any failure by AL001 or ALZN002 to achieve market acceptance or commercial success could have a material adverse effect on our business, results of operations and financial condition.

Problems in the manufacturing process, failure to comply with manufacturing regulations or unexpected increases in manufacturing costs could harm our business, results of operations and financial condition.

We are responsible for the manufacture and supply of AL001 and ALZN002 independently of each other. The manufacturing of AL001 and ALZN002 necessitates compliance with applicable regulatory requirements of the FDA and the European Union, as well as with international cGMP and other international regulatory requirements. As of the date of this Annual Report, we do not have our own manufacturing facilities. We have contracted with a third-party manufacturer for the clinical supply of AL001 using GMP manufacturing for our planned AL001 clinical trials and plan to contract with established third parties for the long-term commercial production of AL001 and ALZN002. The responsibility to obtain market authorization for AL001 and

ALZN002 remains with us. As such, even if we could potentially have a claim against one or more third parties, we are legally liable for any noncompliance related to AL001 and ALZN002 and we expect to retain legal responsibility for any future product candidates as well.

Additionally, we may have limited control over the associated manufacturing costs and potential unexpected increases in those costs over time. If costs increase, we may choose to pass on such costs to our customers, which could reduce our ability to compete by increasing the prices of our products (which we expect to be priced at a significant premium over competing generic products). See "Risks Related to Our Business and Industry — We expect to face substantial competition, with other entities possibly discovering, developing or commercializing products before, or more successfully than, we do." If we cannot pass on all such costs to our customers, then our profitability would be adversely affected.

If we are unable to manufacture, or contract to manufacture, AL001 and ALZN002 in accordance with regulatory specifications, or if there are disruptions in the manufacturing process due to damage, loss or failure to meet regulatory requirements (including passing inspections) of manufacturing facilities, we may not be able to meet the demand for our products or supply sufficient product for use in clinical trials, and this may harm our ability to commercialize AL001 and ALZN002 on a timely or cost-competitive basis, or preclude us from doing so at all, which could harm our business, results of operations and financial condition.

Before we or any future commercial partners can begin commercial manufacture of AL001 and ALZN002 or any other product candidate that we may develop in the future, we must obtain FDA regulatory approval for the product, which requires a successful FDA inspection of our manufacturing facilities (or those we contract with) and the development of quality systems, among other requirements. Even if we successfully pass an FDA Pre-Approval Inspection of any manufacturing facilities we may establish or contract with, our pharmaceutical facilities would be subject to unannounced inspection by the FDA and foreign regulatory authorities to ensure ongoing manufacturing compliance, even after product approval. Due to the complexity of the processes that we anticipate will eventually be used to manufacture AL001 and ALZN002, we may be unable to pass federal, state or international regulatory inspections in a cost-effective manner, whether initially or at any time thereafter. If we are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, or legal actions such as injunctions or criminal or civil prosecution. These possible sanctions could materially and adversely affect our business, results of operations and financial condition. See also "Risks Related to Development and Regulatory Approval of Our Product." The regulatory approval process is uncertain, requires us to utilize significant financial, physical and human resources, and may prevent us or our future commercial partners from obtaining approvals for the commercialization of some or all of our product candidates.

Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of AL001 or ALZN002, or limit the scope of any approved label or market acceptance.

If AL001, ALZN002 or any other product candidate that we may develop in the future, prior to or after any approval for commercial sale, causes serious or unexpected side effects, or become associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, including, without limitation, that:

- regulatory authorities may interrupt, delay or halt clinical trials;
- regulatory authorities may deny regulatory approval of AL001 or ALZN002;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of REMS in connection with approval, if any;
- regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS of any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- any relationships that we may be able to form in the future with any commercial partners may suffer;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that either AL001 or ALZN002 is unlikely to receive regulatory approval or is unlikely to be successfully commercialized. In addition, regulatory agencies, an Ethics Committee or Institutional Review Board (an "IRB"), or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial of AL001, ALZN002 or any other product candidate that we may in the future develop, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing AL001 or ALZN002 and materially impair our ability to generate revenue from the commercialization of AL001 or ALZN002 either by us or by any future commercial partners with which we may develop a relationship, which and could have a material adverse effect on our reputation, business, results of operations and financial condition.

If we fail to obtain and sustain an adequate level of reimbursement for our products by third-party payers, sales and profitability will be adversely affected.

The course of medical treatment for human patients is, and will continue to be, expensive. We expect that most patients and their families will not be capable of paying for our potential products themselves.

Accordingly, it is unlikely that there will be a commercially viable market for AL001 or ALZN002, if approved, without reimbursement and coverage from third-party payers. Obtaining reimbursement approval and coverage from third-party payers is a time consuming and expensive process, and we cannot be certain that reimbursement will be approved and coverage obtained for our current product candidates or any other product candidate we may develop. Additionally, even if there is some form of reimbursement and coverage from third-party payers, if the level of third-party reimbursement is insufficient from the patient's perspective or coverage is limited, our revenue and gross margins will be materially and adversely affected.

A current trend in the U.S. health care industry, as well as in other countries around the world, is toward cost containment. Large public and private payers, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Third-party payers, such as government programs, including Medicare in the United States, and private health care insurers, carefully review and have increasingly been challenging the coverage of, and prices charged for, medical products and services. Many third-party payers limit coverage of or reimbursement for newly-approved health care products. Reimbursement rates and coverage from private health insurance companies vary depending on the company, the insurance plan and other factors. Cost-control initiatives could decrease the price we or our partners establish for products, which could result in lower product revenue and profitability.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Our eventual partners may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals. In many countries, products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may adversely affect our sales and profitability. If countries set prices that are not sufficient to allow us or our partners to generate a profit, our partners may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect our sales and profitability and could materially and adversely affect our business, results of operations and financial condition.

Risks Related to Development and Regulatory Approval of Our Drug Candidates

The regulatory approval process is uncertain, requires us to utilize significant resources, and may prevent us or our future commercial partners from obtaining approvals for the commercialization of AL001 or ALZN002.

The research, testing, manufacturing, labeling, approval, sale, marketing and testing of AL001 and ALZN002 are and will be subject to extensive regulation by regulatory authorities in the United States, Europe and elsewhere, and regulatory requirements applicable to our product differ from country to country. Neither we nor any commercial partner will be permitted to market any of our current or future product candidates in the United States until we receive approval from the FDA of either a NDA or BLA for AL001 and ALZN002, respectively. Obtaining approval of an NDA or a BLA is an uncertain process that requires us to utilize significant resources. Furthermore, regulatory authorities possess broad discretion regarding processing time and usually request additional information and raise questions which have to be answered. There is considerable uncertainty regarding the times at which products may be approved and we have no control over the FDA review process. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including: warning letters, civil and criminal penalties, injunctions, withdrawal of approved products from the market, product seizure or detention, product recalls, total or partial suspension of production, and refusal to approve pending applications or supplements to approved applications.

Even if we fully comply with all applicable laws and regulations, the FDA may still determine that our clinical data are insufficient for final approval of an NDA or BLA. The process required by the FDA and most foreign regulatory authorities before human health care pharmaceuticals may be marketed generally involves nonclinical laboratory and, in some cases, animal tests; submission of an IND, which must become effective before clinical trials may begin; adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses; pre-approval inspection of manufacturing facilities and clinical trial sites; and FDA approval of an NDA or BLA, which must occur before a drug can be marketed or sold.

Regulatory approval of an NDA or BLA, or any supplement thereof, is not guaranteed, and the approval process requires us to utilize significant resources, could take several years, and is subject to the substantial discretion of the FDA. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or have to repeat or perform additional studies. If our product or any of our future product candidates fails to demonstrate safety and efficacy in our studies, or for any other reason does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

In addition, separate regulatory approvals are required in order to market any product in many jurisdictions, including the United States, the United Kingdom, European Economic Area, which consists of the 27 Member States (known as the “EU Member States”) of the European Union plus Norway, Iceland and Liechtenstein, and others. Approval procedures vary among countries and can involve additional studies and testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may be unable to file for regulatory approvals or do so on a timely basis and, even if we are able to, we may not receive necessary approvals to commercialize our products in any market. Any of these results could have a material adverse effect on our business, results of operations and financial condition.

There is a high rate of failure for drug candidates proceeding through clinical trials.

Generally speaking, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. For instance, any such differing interpretation could cause the FDA to require additional trials. In the event that:

(i) we obtain negative or inconclusive results from the AL001 or ALZN002 from a clinical trial;

(ii) the FDA places a clinical hold on our clinical trials due to potential chemistry, manufacturing and controls issues or other hurdles; or

(iii) the FDA does not approve our NDA for AL001 or our BLA for ALZN002, then:

- we may not be able to generate sufficient revenue or obtain financing to continue our operations;
- our ability to execute our current business plan will be materially impaired;
- our reputation in the industry and in the investment community would likely be significantly damaged; and
- the price of our common stock would likely decrease significantly.

Any of these results could materially and adversely affect our business, results of operations or financial condition.

Most attempts at drug approval for Alzheimer’s have failed.

Despite billions of dollars invested by the NIH and the biopharmaceutical industry in research programs to develop novel therapeutics for Alzheimer's, the FDA has only approved three new drugs for Alzheimer's since 2003; in June 2021, aducanumab (Biogen, Inc) received approval from the FDA for the treatment of Alzheimer's using the accelerated approval pathway; in July 2023, Leqembi (Eisai) received full approval by the FDA for treatment of Alzheimer's; and in July 2024, Kisunla (Eli Lilly) received full approval by the FDA for treatment of Alzheimer's. Since 2003, many new types and classes of drugs have been developed and tested in Alzheimer's, including monoclonal antibodies, gamma secretase modulators and inhibitors, β-site amyloid precursor protein cleaving enzyme inhibitors, receptor for advanced glycation end-products inhibitors, nicotinic partial agonists and allosteric modulators, serotonin subtype receptor antagonists, and others. Except for Biogen's, Eisai's and Eli Lilly's approvals, referred to above, virtually all of these scientific programs have failed in clinical testing.

Clinical trials for AL001 or ALZN002 can be expensive, time consuming, uncertain and susceptible to change, delay or termination.

Clinical trials are expensive, time consuming and difficult to design and implement. The result of a clinical trial may be undesirable and can result in a clinical trial cancellation or the need for re-evaluation and supplementation. Even if the results of our clinical trials are favorable, the clinical trials for AL001 or ALZN002 are expected to continue for a few years and may even take significantly longer to complete. In addition, we, the FDA, an IRB, or other regulatory authority, whether in the United States, European Union or elsewhere, may suspend, delay or terminate our clinical trials at any time, for various reasons, including, without limitation:

- lack of effectiveness of AL001 or ALZN002 during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;

- difficulty in retaining subjects who have initiated a clinical trial but may have withdrawn due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to manufacturing or regulatory constraints;
- inadequacy of or changes in our manufacturing process or product formulation;
- delays in obtaining regulatory authorization to commence a trial, including experiencing "clinical holds" or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- changes in applicable regulatory policies and regulations;
- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- unfavorable results from ongoing preclinical studies and clinical trials;
- failure of any CROs that we may partner with in the future, or other third-party contractors, to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, any CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols; or
- regulatory concerns with pharmaceutical products generally and the potential for abuse.

The occurrence of any of the foregoing could have a material adverse effect on our business, results of operations and financial condition. See the risk factor "There is a high rate of failure for drug candidates proceeding through clinical trials" above.

If our products do not receive breakthrough therapy designation, it could potentially increase the FDA's review time and adversely impact our development timeline. Even if the FDA grants breakthrough therapy designation, it does not guarantee faster product development or FDA review and does not necessarily increase the likelihood of the product candidates receiving approval from the FDA.

Breakthrough therapy designation is reserved for drug or biologic products that are intended to treat serious conditions and for which preliminary clinical evidence indicates that the candidate may demonstrate a substantial improvement on one or more clinically significant endpoints over currently available therapies. The benefits of receiving the designation include additional guidance from FDA throughout the development process, assistance with designing clinical trials, and coordination with FDA senior managers and experienced review staff. We plan to seek breakthrough therapy designation for both AL001 and ALZN002. However, we have neither received breakthrough therapy designation nor have we qualified for expedited development, and no assurance can be given that we will. Even if we qualify for breakthrough therapy designation or expedited development, it may not actually lead to faster development or expedited regulatory review and approval or necessarily increase the likelihood that we will receive FDA approval.

Even if we believe that our products are strong candidates for breakthrough therapy designation, it is possible that the FDA may determine that our preliminary clinical evidence is insufficient to justify breakthrough therapy designation. Without this designation, we would not be able to benefit from the increased FDA guidance and assistance throughout the development process, and it is possible that our development timeline could be extended.

The breakthrough therapy designation, while at times advantageous for the development process for the reasons identified above, may nevertheless have little or no positive impact on our development process. There is no guarantee that, even with the FDA's assistance through the breakthrough therapy designation, that the development process will be accelerated, the FDA will review or approve our submissions in a timely manner, or that our product candidates will ultimately receive approval from the FDA.

In summary, we cannot guarantee that our product candidates will receive breakthrough therapy designations and, even if one does, we cannot guarantee that such designations will have any bearing on the FDA's review or approval of our product candidates.

Even if we receive regulatory approval for any of our future product candidates, we will be subject to ongoing FDA and other regulatory body obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if approved, will be subject to labeling and manufacturing requirements and could be subject to other restrictions. Failure to comply with these regulatory requirements or the occurrence of unanticipated problems with our products could result in significant penalties.

Any regulatory approvals that we or any of our collaborators receive for AL001, ALZN002 or any future product candidate may be subject to conditions of approval or limitations on the approved indicated uses for which the product may be marketed or may contain requirements for potentially costly surveillance to monitor the safety and efficacy of the product candidate. In addition, AL001, ALZN002 and any of our future product candidates, if approved by the FDA or other regulatory bodies, will be subject to extensive and ongoing regulatory requirements regarding the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping. These requirements will include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, Good Laboratory Practice and Good Clinical Practice, the three types of audits related to the progressive stages needed to bring a pharmaceutical product to market, for any studies that we conduct post-approval. Later discovery of previously unknown problems with a product, 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 the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on target studies;
- refusal by the FDA or other applicable regulatory body to approve pending applications or supplements to approved applications filed by us or our strategic collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The policies of the FDA and other regulatory bodies may change, and additional government regulations may be promulgated that could prevent, limit or delay regulatory approval of AL001 or ALZN002. 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 elsewhere. 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, which would materially and adversely affect our business, results of operations and financial condition.

AL001 or ALZN002 and any of our future product candidates, if approved, may cause or contribute to adverse medical events that we are required to report to the FDA and regulatory authorities in other countries and, if we fail to do so, we could be subject to sanctions that would materially harm our business.

If we are successful in commercializing AL001, ALZN002 or any of our future product candidates, regulations promulgated by the FDA and by the regulatory authorities in other countries require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA and regulatory authorities in other countries could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products, which could have a material adverse effect on our business, results of operations and financial condition.

Legislative or regulatory reforms with respect to products may make it more difficult and costly for us to obtain regulatory clearance or approval of AL001, ALZN002 or any of our future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in the U.S. Congress and lawmaking bodies in other countries that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Similar changes in regulations can occur in other countries. Any new regulations or revisions or reinterpretations of existing regulations in the United States or in other countries may impose additional costs or lengthen review times of AL001, ALZN002 and any of our future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- requests for additional endpoints or studies;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of certain products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could have a material adverse effect on our ability to obtain regulatory approval for our product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products could materially and adversely affect our business, results of operations and financial condition.

Our ability to market AL001, ALZN002 and any future product candidates in the United States, if approved, will be limited to use for the treatment of the indications for which they are approved, and if we want to expand the indications for which we may market AL001, ALZN002 and any future product candidates, we will need to obtain additional FDA approvals, which may not be granted.

We plan to seek full FDA approval in the United States for AL001 and ALZN002 to treat neurodegenerative diseases and psychiatric disorders,

including Alzheimer's, BD, MDD and PTSD. If AL001 or ALZN002 is approved, the FDA will restrict our ability to market or advertise it for the treatment of indications other than the one for which it is approved, which would limit its use. If we decide to attempt to develop, promote and commercialize new treatment indications and protocols for AL001, ALZN002 and potentially other product candidates in the future, we could not predict when, or if, we would ever receive the approvals required to do so. We would be required to conduct additional studies to support such applications for additional use, which would consume additional resources and may produce results that do not result in FDA approvals. If we do not obtain additional FDA approvals, our ability to expand our business in the United States would be adversely affected, which could materially and adversely affect our business, results of operations and financial condition.

The anticipated development of a REMS for AL001 or ALZN002 could cause delays in the approval process and would add additional layers of regulatory requirements that could impact our ability to commercialize AL001 and ALZN002 in the United States and reduce their market potential.

As a condition of approval of an NDA or a BLA, the FDA may require a REMS to ensure that the benefits of the drug outweigh the potential risks. REMS elements can include medication guides, communication plans for health care professionals, and elements to assure safe use ("ETASU"). ETASU's can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. We may be required to adopt a REMS for AL001 or ALZN002 to ensure that the benefits outweigh the risks of abuse, misuse, diversion and other potential safety concerns. Even if the risk of abuse, misuse or diversion are not as high as for some other products, there can be no assurance that the FDA will approve a manageable REMS for AL001 or ALZN002, which could create material and significant limits on our ability to successfully commercialize AL001 and ALZN002 in the U.S. Delays in the REMS approval process could result in delays in the NDA or BLA approval process, respectively. In addition, as part of the REMS, the FDA could require significant restrictions, such as restrictions on the prescription, distribution and patient use of the product, which could significantly impact our ability to effectively commercialize AL001 or ALZN002, and dramatically reduce their market potential thereby adversely impacting our business, financial condition and results of operations. Even if initial REMS are not highly restrictive, if, after launch, AL001, ALZN002 and other drug candidates were to become subject to significant abuse/non-medical use or diversion from licit channels, this could lead to negative regulatory consequences, including a more restrictive REMS, which could materially and adversely affect our business, results of operations and financial condition.

If we are found in violation of "fraud and abuse" laws, we may be subject to criminal and civil penalties and/or be suspended or excluded from participation in government-run health care programs, which may adversely affect our business, financial condition and results of operations.

If we are successful in obtaining marketing approval for our products in the United States and elsewhere, we will be subject to various health care "fraud and abuse" laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in government-run health care programs, which could materially and adversely affect us, particularly upon successful commercialization of our products in the United States. For example, the federal Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a U.S. health care program such as Medicare or Medicaid. Under U.S. federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the Anti-Kickback Statute. Compliance with every element of a safe harbor regulation is required for the arrangement to be protected. However, arrangements that do not comply with a safe harbor are not per se illegal. Instead, they will be analyzed on a case-by-case basis. Although we intend to seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the Anti-Kickback Statute and similar laws in other jurisdictions.

Further, false claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, reimbursement claims for drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the payment of kickbacks by pharmaceutical providers has resulted in the submission of false claims to governmental health care programs. Under laws such as the Health Insurance Portability and Accountability Act of 1996 in the United States, we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from government-run health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. and other governments. In addition, in the United States, individuals have the ability to bring actions on behalf of the government and potentially share in the recovery under the federal False Claims Act as well as under state false claims laws.

Many states in the United States have adopted fraud and abuse laws similar to their federal counterparts, including laws similar to the Anti-Kickback Statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payers. In addition, California and some other states in the United States have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals. In addition, several states impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

We have yet to receive definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our future practices may be challenged under these laws. While we believe we will be able to structure our business arrangements to comply with these laws, it is possible that the government could in the future allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in certain government-run health care programs, and our business, results of operations and financial condition may be materially and adversely affected.

Risks Related to Our Business and Industry

If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop AL001, ALZN002 or any future product candidates, conduct our in-licensing and development efforts or commercialize AL001, ALZN002 or any of our future product candidates.

Our future growth and success depend in part on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Stephan Jackman, our Chief Executive Officer, David J. Katzoff, our Chief Financial Officer, Kenneth S. Cragun, our Senior Vice President of Finance and Henry Nisser, our Executive Vice President and General Counsel. The loss of services of any of these individuals could delay or prevent the successful development of our current or future product pipeline, completion of our planned development efforts or the commercialization of AL001 or ALZN002. It is possible that current or former employees of ours could put forward claims for an alleged right to our patents and demand compensation therefor. If one or more of the key personnel were to leave us and engage in competing operations, our business, results of operations and financial condition could be materially and adversely affected.

We expect to face substantial competition, with other entities possibly discovering, developing or commercializing products before, or more successfully than, we do.

The development, FDA approval and commercialization of new therapy and vaccine products is highly competitive. We will face competition with respect to AL001, ALZN002 and any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. In addition to existing therapeutic treatments for the indications we are targeting with AL001 and ALZN002, we also face potential competition from other drug candidates in development by other companies. Our potential competitors include, without limitation, large health care companies, such as Biogen Inc., Eisai Co., Ltd., Takeda Pharmaceuticals, Bristol Myers Squibb, Pfizer Inc., Merck & Co., Inc., Sanofi S.A., Eli Lilly and Company, Bayer AG, Novartis AG, Johnson and Johnson and Boehringer Ingelheim GmbH. We also know of several smaller early-stage companies that are developing products for use in our segment of the market. Some of the potential competitive compounds referred to above are being developed by large, well-financed and established pharmaceutical and biotechnology companies or have been partnered with such companies, which may give them development, regulatory and marketing advantages over our products.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products. If AL001 or ALZN002 achieves marketing approval, we expect that it will be priced at a significant premium over competing generic products.

Some of the companies against which we are competing or against which we may compete in the future have significantly greater financial, physical and human resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to compete successfully, we may be unable to grow and sustain our revenue, which could materially and adversely affect our business, results of operations and financial condition.

Changes in funding for the FDA and other government agencies could hinder their ability to hire and retain key leadership and other personnel, or otherwise prevent our product candidates from being developed or commercialized in a timely manner, which could negatively impact our business.

We rely on the FDA to assist with the development of our product candidates. The ability of the FDA to review and approve new drug products can be affected by a variety of factors outside of our control, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for our product candidates to be reviewed and/or potentially approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. If the timing of FDA's review and approval of new products is delayed, the estimated timing of our drug development program may be delayed which would materially increase costs of drug development and harm our operations or business.

Risks Related to Our Intellectual Property

We may be forced to litigate to enforce or defend our intellectual property rights, or the intellectual property rights of our licensors.

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors. In so doing, we may place our intellectual property at risk of being invalidated, held unenforceable, or narrowed in scope. Further, an adverse result in any litigation or defense proceedings may place pending applications at risk of non-issuance. In addition, if any licensor fails to enforce or defend its intellectual property rights, this may adversely affect our ability to develop and commercialize AL001 or ALZN002 as well as our ability to prevent competitors from making, using, and selling competing products. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence or outcome of any such litigation could harm our business, results of operations and financial condition.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary 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 material adverse effect on the price of our common stock.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other products that compete with our products or cause additional, material adverse effects upon our business, results of operations and financial

condition.

The transfer of technology and knowledge to contract manufacturers pursuant to the production of our products also creates a risk of uncontrolled distribution and copying of concepts, methods and processes relating to our products. Such uncontrolled distribution and copying could have a material adverse effect on the value of our products if used for the production of competing drugs or otherwise used commercially without our obtaining financial compensation.

We may become subject to third parties' claims alleging infringement of patents and proprietary rights or seeking to invalidate our patents or proprietary rights, which would be costly, time-consuming and, if successfully asserted against us, delay or prevent the development and commercialization of AL001 or ALZN002.

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry, as well as patent challenge proceedings, including interference and administrative law proceedings before the USPTO and the European Patent Office ("EPO"), and oppositions and other comparable proceedings in other jurisdictions. Recently, under U.S. patent reform laws, new procedures including inter partes review and post grant review have been implemented. As stated below, the novel implementation of such laws presents uncertainty regarding the outcome of challenges to our patents in the future.

We cannot assure you that AL001, ALZN002 or any of our future product candidates will not infringe existing or future patents. We may be unaware of patents that have already been issued that a third party might assert are infringed by AL001, ALZN002 or one of our future product candidates. Because patent applications can take many years to issue and may be confidential for 18 months or more after filing, there may be applications now pending of which we are unaware of and which may later result in issued patents that we may infringe by commercializing AL001, ALZN002 or any of our future product candidates. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may face claims from non-practicing entities (commonly referred to as patent trolls), which have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay research, development, manufacturing or sales of AL001 or ALZN002. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. Even if we are successful in defending such claims, infringement and other intellectual property litigation can be expensive and time-consuming to litigate and divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference proceedings in the USPTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents in the USPTO. We may also become involved in similar opposition proceedings in the EPO or comparable offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Any of these claims could have a material adverse effect on our business, results of operations and financial condition.

If our efforts to protect the proprietary nature of the intellectual property related to AL001, ALZN002 or any of our potential future product candidates are not adequate, we may not be able to compete effectively in our market.

We expect to rely upon a combination of patents, trade secret protection as well as confidentiality and license agreements to protect the intellectual property related to our product and our current product candidates and our development programs.

Composition-of-matter patents on an active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any particular method of use or manufacture. We cannot be certain that the claims in any patent application that we may submit covering composition-of-matter of AL001, ALZN002 and any potential future product candidates will be considered patentable by the USPTO and courts in the U.S., or by the patent offices and courts in foreign countries. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method.

The strength of patents involves complex legal and scientific questions and can be uncertain. The patent applications that we may in the future own or license may fail to result in issued patents in the United States or in other foreign countries. Even if the patents are successfully issued, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, any of our future patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we may own, license or pursue with respect to AL001, ALZN002 or any future product candidates is threatened, it could threaten our ability to commercialize AL001, ALZN002 or any future product candidates. Further, if we encounter delays in our development efforts, the period of time during which we could market AL001, ALZN002 or any future product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to AL001, ALZN002 or any future product candidates.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have.

We will also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or had access to our proprietary information, nor that our agreements will not be breached. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the United States or the European Union. As a result, we may encounter significant problems in protecting and defending our intellectual property not only in the United States and

the European Union, but elsewhere as well. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially and adversely affect our business, results of operations and financial condition and any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect AL001 and ALZN002.

As is the case with other biopharmaceutical companies, our success will be heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in other situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in ways that would weaken our ability to obtain patents and to enforce patents that we might obtain in the future. Similarly, changes in EU patent law and elsewhere could negatively affect the value of our patents registered outside of the U.S.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with any of these requirements.

The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, which could have a material adverse effect on our business, results of operations and financial condition.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on AL001, ALZN002 and any future product candidates throughout the world is prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Risks Relating to Legal Matters

If product liability lawsuits are brought against us, we will incur substantial liabilities and may be required to limit the commercialization of AL001 or ALZN002.

We and our partners face potential product liability exposure related to the testing of AL001 or ALZN002 in clinical trials. We will face exposure to claims by an even greater number of persons if we begin to market and distribute our products commercially in the U.S. and elsewhere, including those relating to misuse of AL001 or ALZN002. Now, and in the future, an individual may bring a liability claim against us alleging that AL001 or ALZN002 caused an injury. While we intend to take what we believe to be appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Even if we successfully defend any such action, the costs associated with such defense could prove exorbitant. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for AL001 or ALZN002 (if such product candidate had been approved and gone to market);
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- increased cost of liability insurance;
- loss of revenue; and
- our inability to successfully commercialize our products.

Further, in the future there may be a need to expand the scope of our insurance coverage, which could result in significantly increased costs or the inability to obtain sufficient insurance coverage. Any of these occurrences could have a material adverse effect on our business, results of operations and financial condition.

Risks Related to Our Affiliates' Control and Relationships

Insiders currently have substantial influence over us, which could limit your ability to affect the outcome of key transactions, including a change of control.

In the aggregate, beneficial ownership of the shares of our common stock by our directors and executive officers and their respective affiliated parties represents approximately 60.5% of the outstanding shares of our common stock. As a result, these stockholders, if they act together, will be able to influence our management and affairs and all matters requiring stockholder approval, including the election of directors and approval of significant

corporate transactions. This concentration of ownership may have the effect of delaying or preventing a change in control of our company and might affect the market price of our common stock.

Members of the Board of Directors and executive officers of our company and AULT, contain some of the same individuals, which may present potential conflicts of interest.

Milton C. (Todd) Ault III, our Founder, and Vice Chairman, has significant influence over our Company, directly and indirectly through his controlling equity interest in Ault & Company, Inc. ("Ault & Co."), the parent of Ault Life Sciences, Inc. ("ALSI") and Ault Life Sciences Fund, LLC ("ALSF"). Mr. Ault is also the Executive Chairman and single largest stockholder (through his control of Ault & Co.) of AULT, a publicly traded diversified holding company focused primarily on digital mining of Bitcoin and its crane services, defense/aerospace, industrial, automotive, medical/biopharma, hotel operations and textiles. The Board of Directors ("Board") and executive officers of our company and the board of directors and executive officers of AULT contain some of the same individuals, all of whom devote a portion of their business and professional time and efforts to the respective businesses of our company as well as AULT. In addition to Mr. Ault, William B. Horne, the Chairman of the Board, is the Chief Executive Officer and a director of AULT, Henry Nisser, our Executive Vice President, General Counsel and a director of our company, is the President, General Counsel and a director of AULT and Kenneth S. Cragun, our Senior Vice President of Finance is the Chief Financial Officer of AULT.

While we believe that our business and technologies are distinguishable from those of AULT and that we do not compete in the markets in which AULT compete, Mr. Ault and the other named individuals may have potential conflicts of interest with respect to, among other things, potential corporate opportunities, business combinations, joint ventures and/or other business opportunities that may become available to them, our company or AULT. Moreover, while Mr. Ault and the other named individuals have agreed to devote a portion of their business and professional time and efforts to our company, potential conflicts of interest also include the amount of time and effort devoted by each of them to the affairs of AULT. We may be materially adversely affected if Mr. Ault and/or the other named individuals choose to place the interests of AULT before those of our company. Each of Mr. Ault and the other named individuals has agreed that, to the extent such opportunities arise, he will carefully consider a number of factors, including whether such opportunities were presented to him in his capacity as an officer or director of our company, whether such opportunities are within our company's line of business or consistent with our strategic objectives and whether our company will be able to undertake or benefit from such opportunities. In addition, our Board has adopted a policy whereby any future transactions between us and any of our affiliates, officers, directors, principal stockholders or any affiliates of the foregoing will be on terms no less favorable to our company than could reasonably be obtained in "arm's length" transactions with independent third parties, and any such transactions will also be approved by a majority of our disinterested independent directors. Each of Mr. Ault and the other named individuals owe fiduciary duties of good faith, care and loyalty to our company under Delaware law. However, the failure of our management to resolve any conflicts of interest in favor of our company could materially adversely affect our business, financial condition and results of operations.

Certain provisions of our certificate of incorporation allow concentration of voting power, which may, among other things, delay or frustrate the removal of incumbent directors or a takeover attempt, even if such events may be beneficial to our stockholders.

Provisions of our certificate of incorporation may delay or frustrate the removal of incumbent directors and may prevent or delay a merger, tender offer or proxy contest involving our company that is not approved by our Board, even if those events may be perceived to be in the best interests of our stockholders. Further, we may designate and issue separate classes of preferred stock that may entitle their holder(s) to exercise significant control over us. Consequently, anyone to whom or which these shares are or were issued could have sufficient voting power to significantly influence if not control the outcome of all corporate matters submitted to the vote of our common stockholders. Those matters could include the election of directors, changes in the size and composition of our Board, and mergers and other business combinations involving us. In addition, through any such person's control of our Board and voting power, the affiliate may be able to control certain decisions, including decisions regarding the qualification and appointment of officers, dividend policy, access to capital (including borrowing from third-party lenders and the issuance of additional debt or equity securities), and the acquisition or disposition of assets by us. In addition, the concentration of voting power in the hands of an affiliate could have the effect of delaying or preventing a change in control of our company, even if the change in control could benefit our stockholders and may adversely affect the future market price of our common stock should a trading market therefor develop.

Risks Relating to Ownership of Our Common Stock

We are not in compliance with the Nasdaq continued listing requirements. If we are unable to comply with the continued listing requirements of The Nasdaq Capital Market, our Common Stock could be delisted, which would adversely affect our Common Stock's market price and liquidity and reduce our ability to raise capital.

On September 26, 2023, we were notified by the staff of The Nasdaq Stock Market LLC ("Nasdaq") that for the previous 30 consecutive trading days, the minimum Market Value of Listed Securities ("MVLS") for our common stock was below the $35 million minimum MVLS requirement for continued listing on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(b)(2) (the "MVLS Rule"). In accordance with Listing Rule 5810(c)(3)(C), we were provided 180 calendar days, or until March 25, 2024, to regain compliance with the MVLS Rule.

On March 26, 2024, we were notified by Nasdaq that we had not regained compliance with the MVLS Rule. As a result, unless we requested an appeal of this determination, Nasdaq determined that our common stock would be scheduled for delisting from The Nasdaq Capital Market and would be suspended at the opening of business on April 4, 2024 and a Form 25-NSE would be filed with the SEC. On April 2, 2024, we requested a hearing before a Hearings Panel (the "Panel") to appeal the determination. The Panel heard our appeal at a hearing on May 9, 2024. On May 21, 2024, we received notice from the Panel that it granted our request to continue our listing on Nasdaq, subject to us demonstrating compliance, on or before September 23, 2024, with Listing Rule 5550(b)(1), which requires stockholder equity of at least $2.5 million (or an alternative listing standard), and satisfying all applicable requirements for continued listing on Nasdaq. There can be no assurance as to our ability to demonstrate compliance on or before September 23, 2024.

In addition, on February 1, 2024, we received a notice in the form of a letter from Nasdaq stating that we were not in compliance with Nasdaq Listing Rule 5550(a)(2) because the bid price for our common stock had closed below $1.00 per share for the previous 30 consecutive business days.

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have 180 calendar days, or until July 30, 2024, to regain compliance with the Nasdaq Listing Rule 5550(a)(2). The deficiency letter states that to regain compliance, the bid price for our common stock must close at $1.00 per share or more for a minimum of 10 consecutive business days (the "Minimum Bid Price") during the compliance period ending July 30, 2024. In the event that we do not regain compliance within this 180-day period, we may be eligible to seek an additional compliance period of 180 calendar days if we meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for The Nasdaq Capital Market, with the exception of the Minimum Bid Price, and provide written notice to Nasdaq of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. However, if it appears to the Nasdaq staff that we will not be able to cure the deficiency, or if we are otherwise ineligible, Nasdaq will provide us with notice that our common stock will be subject to delisting. At that time, we may appeal any such delisting determination to a Nasdaq

hearings panel. The deficiency letter has no immediate effect on the listing of our common stock, and our common stock will continue to trade on The Nasdaq Capital Market under the symbol “ALZN.”

Effective July 16, 2024, we effected a one-for-ten reverse stock split of our common stock, with the intent to achieve compliance with the Minimum Bid Price requirement. While we are exercising diligent efforts to maintain the listing of our common stock on Nasdaq, there can be no assurance that we will be able to regain compliance with the Minimum Bid Price or maintain compliance with the other Nasdaq listing standards.

If our common stock is delisted, it could be more difficult to buy or sell our common stock and to obtain accurate quotations, and the price of our common stock could suffer a material decline. Delisting could also impair the liquidity of our common stock and could harm our ability to raise capital through alternative financing sources on terms acceptable to us, or at all, and may result in potential loss of confidence by investors, employees, and fewer business development opportunities.

We do not know whether an active market will be sustained; as a result, it may be difficult for you to sell your shares of our common stock.

If an active market for our common stock is not sustained, it may be difficult for you to sell your shares of common stock at an attractive price or at all. We cannot predict the prices at which our common stock will trade. It is possible that in one or more future periods our results of operations and progression of our product pipeline may not meet the expectations of public market analysts and investors and, as a result of these and other factors, the price of our common stock may fall.

The market price of our common stock is volatile, which could result in substantial losses for investors.

Our common stock is listed on the Nasdaq Capital Market. Since our initial public offering last year, our trading price has fluctuated widely, depending on many factors that may have little to do with our operations or business prospects. During the year ended April 30, 2024, our stock closed at prices between $6.76 per share and $115.95 per share, as reported on Nasdaq.com.

Stock markets, in general, have experienced, and continue to experience, significant price and volume volatility, and the market price of our common stock may continue to be subject to similar market fluctuations unrelated to our operating performance or prospects. This increased volatility, coupled with depressed economic conditions, could continue to have a depressive effect on the market price of our common stock. The following factors, many of which are beyond our control, may influence our stock price:

- announcements of the failure to obtain regulatory approvals or receipt of a “complete response letter” from the FDA;
- announcements of restricted label indications or patient populations, or changes or delays in regulatory review processes;
- announcements of therapeutic innovations or new products by us or our competitors;
- adverse actions taken by regulatory agencies with respect to our clinical trials, manufacturing supply chain or sales and marketing activities;
- changes or developments in laws or regulations applicable to our product candidates;

- any failure of our testing and clinical trials;
- product liability claims, other litigation or public concern about the safety of our product candidates or future products;
- any adverse changes to our relationship with licensors, manufacturers or suppliers;
- the loss of any of our key scientific or management personnel;
- any major changes to our Board or management;
- the failure to obtain new commercial partners;
- announcements concerning our competitors or the pharmaceutical industry in general;
- the failure to achieve expected product sales and profitability;
- the failure to obtain reimbursements for our product candidates as part of any healthcare insurance plan, or reductions in such reimbursements;
- actual or anticipated fluctuations in our cash position or operating results;
- manufacturing, supply or distribution shortages related to our current or future product candidates for our development programs and commercialization;
- changes in financial estimates or recommendations by securities analysts;
- the termination of any of our existing license agreements;
- announcements relating to future licensing or development agreements;
- potential acquisitions;
- the trading volume of shares on The Nasdaq Capital Market;
- sales of our shares by us, our executive officers or directors or our shareholders;
- fluctuations in the U.S. equity markets;
- changes in accounting principles;
- market conditions in the healthcare sector; and

- general economic conditions in the United States and elsewhere.

In recent years, each of the stock market in general, and the market for pharmaceutical and biotechnology companies in particular, has experienced significant price and volume fluctuations that have often been unrelated or disproportionate to changes in the operating performance of the companies whose stock is experiencing those price and volume fluctuations. Broad market and industry factors may seriously affect the market price of our common stock, regardless of our actual operating performance. Following periods of such volatility in the market price of a company's securities, securities class action litigation has often been brought against that company. Because of the potential volatility of our stock price, we may become the target of securities litigation in the future. Securities litigation could result in substantial costs and divert management's attention and resources from our business.

If there are substantial sales of shares of our common stock, the price of our common stock could decline.

The price of our common stock could decline if there are substantial sales of our common stock, particularly sales by our directors, executive officers and significant stockholders, or if there is a large number of shares of our common stock available for sale and the market perceives that sales will occur. As of July 29, 2024, we had 841,240 shares of our common stock outstanding. Shares held by directors, executive officers and other affiliates will be subject to volume limitations under Rule 144 under the Securities Act and various vesting agreements. We have registered shares of common stock that we have issued and may issue under our employee equity incentive plans, which shares may be sold freely in the public market upon issuance. Sales of our common stock by current stockholders may make it more difficult for us to sell equity or equity-related securities in the future at a time and price that we deem reasonable or appropriate, and make it more difficult for other stockholders to sell shares of our common stock.

The market price of the shares of our common stock could decline as a result of the sale of a substantial number of our shares of common stock in the public market or the perception in the market that the holders of a large number of shares intend to sell their shares. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

The concentration of our stock ownership will limit your ability to influence corporate matters, including the ability to influence the outcome of director elections and other matters requiring stockholder approval.

Our executive officers, directors and the holders of more than 5% of our outstanding common stock, in the aggregate, beneficially own a significant percentage of our common stock. As a result, these stockholders, acting together, will have significant influence over all matters that require approval by our stockholders, including the election of directors and approval of significant corporate transactions. Corporate actions might be taken even if other stockholders oppose them. This concentration of ownership might also have the effect of delaying or preventing a change of control of our company that other stockholders may view as beneficial.

Our bylaws provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States are the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our bylaws provides that the Court of Chancery of the State of Delaware will be the exclusive forum for any derivative action or proceeding brought on our behalf; any action asserting a breach of fiduciary duty; any action asserting a claim against us arising under the Delaware General Corporation Law, our certificate of incorporation or our bylaws; any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or our bylaws; and any action asserting a claim against us that is governed by the internal affairs doctrine. This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Our bylaws further provide that the federal district courts of the United States will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. The enforceability of similar exclusive federal forum provisions in other companies' organizational documents has been challenged in legal proceedings, and while the Delaware Supreme Court has ruled that this type of exclusive federal forum provision is facially valid under Delaware law, there is uncertainty as to whether other courts would enforce such provisions and that investors cannot waive compliance with the federal securities laws and 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, officers or other employees, which may discourage such lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find either exclusive forum provision in our bylaws to be inapplicable or unenforceable in an action, we may incur further significant additional costs associated with resolving such action in other jurisdictions, all of which could have a material adverse effect on our business, financial condition, and results of operations.

General Risk Factors

We must effectively manage the growth of our operations, or our company will suffer.

Our initiation of operations has resulted in significantly higher operating expenses. Expansion of our operations, to include the development of AL001 and ALZN002, may also cause a significant demand on our management, finances and other resources. Our ability to manage the anticipated future growth, should it occur, will depend upon a significant expansion of our accounting and other internal management systems and the implementation and subsequent improvement of a variety of systems, procedures and controls. In addition, we intend to expand our scientific advisory board. There can be no assurance that significant problems in these areas will not occur. Any failure to expand these areas and implement and improve AL001 or ALZN002 or our procedures and controls in an efficient manner at a pace consistent with our business could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that our attempts to expand our marketing, sales, manufacturing and customer support efforts will be successful or will result in additional sales or profitability in any future period.

We may not be successful in our efforts to expand our pipeline of product candidates.

One element of our strategy is to expand our pipeline of pharmaceuticals based on our technology and advance these product candidates through clinical development for the treatment of a variety of indications. Although our research and development efforts to date have resulted in a number of development programs based on our technology, we may not ultimately be able to develop product candidates that are safe and effective. Even if we are successful in continuing to expand our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. In addition, if we attempt to apply our technology to develop product candidates for indications outside of Alzheimer's, we will need to evaluate the preclinical data and determine if additional data are needed to support the new indications. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenue in future periods, which would make it unlikely that we would ever achieve profitability.

We may experience product recalls or inventory losses caused by unforeseen events, cold chain interruption and testing difficulties.

AL001 and ALZN002, individually, will be manufactured and distributed, if ever, using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as the strict company and government standards for the manufacture of our products, will subject us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Most of our products must be stored and transported at temperatures within a certain range, which is known as "strict cold chain" storage and transportation. If these environmental conditions deviate from the norm, our products' remaining shelf lives could be impaired or their quality could become adversely affected, making them no longer suitable for use. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches, any of which could have a material adverse effect on our business, results of operations and financial condition.

Because we do not intend to pay dividends on our common stock, you must rely on stock appreciation for any return on your investment.

We presently intend to retain any future earnings and do not expect to pay any dividends in the foreseeable future. As a result, you must rely on stock appreciation and a liquid trading market for any return on your investment. If an active and liquid trading market does not develop, you may be unable to sell your shares of common stock at or above the initial public offering price or at the time you would like to sell.

We have identified a material weakness in our internal control over financial reporting. If our remediation of this material weakness is not effective, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls in the future, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our common stock.

We have limited accounting personnel to adequately execute our accounting processes and other supervisory resources with which to address our internal control over financial reporting. In connection with the audit of our financial statements for the year ended April 30, 2024, we identified material weaknesses in our internal control over financial reporting. A material weakness is a deficiency, or 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 related to a lack of sufficient number of qualified personnel within our accounting function to adequately segregate duties, to perform sufficient reviews and approval of manual journal entries posted to the general ledger and to consistently execute review procedures over general ledger account reconciliations, financial statement preparation and accounting for non-routine transactions and, we have not designed and implemented effective Information Technology General Controls ("ITGC") related to access controls to payment and financial accounting systems.

We are implementing measures designed to improve our internal control over financial reporting to remediate this material weakness, including the following:

- We are formalizing our internal control documentation and strengthening supervisory reviews by our management;
- We are in the process of adding additional accounting personnel and segregating duties amongst accounting personnel; and
- We are in the process of strengthening ITGC access controls related to our payment and financial accounting systems.

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not correct the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected on a timely basis.

As a public company, we are required to maintain internal control over financial reporting and to report any material weaknesses in such internal controls. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act. The Sarbanes-Oxley Act also requires that our management report on internal control over financial reporting be attested to by our independent registered public accounting firm, to the extent we are no longer an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (JOBS Act). We do not expect our independent registered public accounting firm to attest to our management report on internal control over financial reporting for so long as we are an emerging growth company.

We are in the process of enhancing our internal control over financial reporting required to comply with this obligation, which process will be time consuming, costly and complicated. If we identify any additional material weaknesses in our internal control over financial reporting, if we are unable to comply with the requirements of Section 404 in a timely manner, if we are unable to assert that our internal control over financial reporting is effective, or when required in the future, if our independent registered public accounting firm is unable to express an opinion as to the effectiveness of our internal control over financial reporting, investors may lose confidence in the accuracy and completeness of our financial reports and the market price of our common stock could be adversely affected, and we could become subject to investigations by the Nasdaq Stock Market, the SEC, or other regulatory authorities, which could require additional financial and management resources.

We may have trouble hiring additional qualified personnel.

As we expand our development and commercial activities, we will need to hire additional personnel and could experience difficulties attracting and retaining qualified employees. Competition for qualified personnel in the biopharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by that industry. We may not be able to attract and retain quality personnel on favorable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that such personnel have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. Any of these difficulties could have a material adverse effect on our business, results of operations and financial condition.

Failure of our information technology systems could significantly disrupt the operation of our business.

Our ability to execute our business plan and to comply with regulatory requirements with respect to data control and data integrity depends, in part, on the continued and uninterrupted performance of our information technology systems, or IT systems. These systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive

problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, there are no assurances that electronic break-ins, computer viruses and similar disruptive problems, and/or sustained or repeated system failures or problems arising during the upgrade of any of our IT systems that interrupt our ability to generate and maintain data will not occur. The occurrence of any of the foregoing with respect to our IT systems could have a material adverse effect on our business, results of operations or financial condition.

We are subject to various claims and legal actions arising in the ordinary course of our business.

We are subject to various claims and legal actions arising in the ordinary course of our business. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence of any such litigation could harm our business, results of operations and financial condition. Results of actual and potential litigation are inherently uncertain. An unfavorable result in a legal proceeding could adversely affect our reputation, financial condition and operating results.

We will be subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our anticipated operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations, if initiated, will be subject to certain anti-corruption laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), and other anti-corruption laws that apply in countries where we do business. The FCPA and other anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and any future commercial partners may operate in a number of jurisdictions that pose a high risk of potential FCPA violations and we may participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We also anticipate becoming subject to other laws and regulations governing our international operations, including regulations administered in the U.S. and in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively, "Trade Control Laws").

There can be no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws, including the FCPA or other legal requirements, such as Trade Control Laws. Any investigation of potential violations of the FCPA, other anti-corruption laws or Trade Control Laws by the United States, the European Union or other authorities could have an adverse impact on our reputation, our business, results of operations and financial condition. Furthermore, should we be found not to be in compliance with the FCPA, other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, as well as the accompanying legal expenses, any of which could have a material adverse effect on our reputation and liquidity, as well as on our business, results of operations and financial condition.

Certain provisions of our certificate of incorporation, bylaws and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in the stockholders' interest.

Our certificate of incorporation, bylaws and certain provisions of Delaware law could have the effect of making it more difficult or more expensive for a third party to acquire, or discouraging a third party from attempting to acquire, control of our company, even when these attempts may be in the best interests of our stockholders. For example, we are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A "business combination" includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation's outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in control of our company.

Failure to build our finance infrastructure and improve our accounting systems and controls could impair our ability to comply with the financial reporting and internal controls requirements for publicly traded companies.

As a public company, we operate in an increasingly demanding regulatory environment, which requires us to comply with the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, the regulations of The Nasdaq Capital Market, the rules and regulations of the SEC, expanded disclosure requirements, accelerated reporting requirements and more complex accounting rules. Company responsibilities required by the Sarbanes-Oxley Act include establishing corporate oversight and adequate internal control over financial reporting and disclosure controls and procedures. Effective internal controls are necessary for us to produce reliable financial reports and are important to help prevent financial fraud. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting, as required by Section 404 of the Sarbanes-Oxley Act.

We anticipate that the process of building our accounting and financial functions and infrastructure will require significant additional professional fees, internal costs and management efforts. We expect that we will need to implement a new internal system to combine and streamline the management of our financial, accounting, human resources and other functions. However, such a system would likely require us to complete many processes and procedures for the effective use of the system or to run our business using the system, which may result in substantial costs. Any disruptions or difficulties in implementing or using such a system could adversely affect our controls and harm our business. Moreover, such disruption or difficulties could result in unanticipated costs and diversion of management attention. In addition, we may discover weaknesses in our system of internal financial and accounting controls and procedures that could result in a material misstatement of our financial statements. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If we cannot provide reliable financial reports or prevent fraud, our business and results of operations could be harmed, investors could lose confidence in our reported financial information and we could be subject to sanctions or investigations by The Nasdaq Capital Market, the SEC or other regulatory authorities.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our common stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. We do not currently have and may never obtain research coverage by industry or financial analysts. If no or few analysts commence coverage of us, the trading price of our common stock could decrease. Even if we do obtain analyst coverage, if one or more of the analysts covering our business

downgrade their evaluations of our stock, the price of our common stock could decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our common stock, which in turn could cause our stock price to decline.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. For so long as we remain an emerging growth company, we are permitted and plan to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include not being required to comply with the auditor attestation requirements of SOX Section 404, not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, reduced disclosure obligations regarding executive compensation, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, the information we provide stockholders will be different than the information that is available with respect to other public companies. In this Annual Report, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer an emerging growth company (or, to a lesser extent, a smaller reporting company), we will incur significant legal, accounting, and other expenses that we did not incur as a private company. Sarbanes-Oxley Act of 2002, 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 establishment and maintenance of effective disclosure and financial controls and corporate governance practices. We expect that we will need to hire additional accounting, finance, and other personnel in connection with our becoming, and our efforts to comply with the requirements of being, a public company, and our management and other personnel will need to devote a substantial amount of time towards maintaining compliance with these requirements. These requirements will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. For example, we expect that the rules and regulations applicable to us as a public company may make it more difficult and more expensive for us to obtain director and officer liability insurance, which could make it more difficult for us to attract and retain qualified members of our Board. We are currently evaluating these rules and regulations and 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 charter provides for limitations of director liability and indemnification of directors and officers and employees.

Our certificate of incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify our directors, officers and employees to the fullest extent permitted by law. Our bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding. We believe that these provisions are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability in our certificate of incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might provide a benefit to us and our stockholders. Our results of operations and financial condition may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biopharmaceutical companies have experienced significant stock price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

Information Security Program

The mission of our information security program is to design, implement, and maintain a comprehensive information security program that protects our systems, services, and data against unauthorized access, disclosure, modification, damage, and loss. Our information security program is

comprised of internal and external security and technology professionals who work collaboratively to identify, assess, manage, and mitigate cybersecurity risks and threats across the Company and third-party contractors.

We recognize the importance of effectively managing material risks associated with cybersecurity threats, as defined in Item 106(a) of Regulation S-K. Our risk management program integrates the monitoring and management of these risks and threats and is informed by applicable laws, regulations, industry standards, and best practices. We continue to invest in information security resources to mature, expand, and adapt our capabilities to address emerging cybersecurity risks and threats.

Our information security organization is committed to maintaining a robust and resilient security posture that enables us to protect our assets, maintain our stakeholders' trust, and support our business's overall success.

Cybersecurity Risk Management and Strategy

Our cybersecurity risk management and strategy are integral components of our comprehensive information security program. They guide our continuous efforts to evaluate and improve the confidentiality, integrity, and availability of our critical systems, data, and operations.

We have adopted an Information Security Policy (the “Info-Sec Policy”) and an Incident Response Plan (the “Response Plan”) that establish administrative, physical, and technical controls and procedures to protect sensitive data throughout the Company. These policies also outline processes to assess, identify, manage, and report cybersecurity risks and incidents. The Info-Sec Policy applies to all persons working for the Company and any third parties working with us in any capacity.

Our approach to controls and risk management is informed by applicable laws and regulations, as well as industry standards and best practices. These serve as a guide to help us identify, assess, and manage cybersecurity controls and risks relevant to our business.

Our cybersecurity risk management program includes:

1. Identifying cybersecurity risks that could impact our facilities, third-party vendors/partners, operations, critical systems, information, and broader enterprise information technology environment. Risks are informed by threat intelligence, current and historical adversarial activity, and industry-specific threats;

2. Performing cybersecurity risk assessments to evaluate our readiness if the risks were to materialize;

3. Ensuring risk is addressed and tracking any necessary remediation through an action plan;

4. Analyzing all third-party vendors for compliance with our internal Info-Sec Policy to assess potential risks associated with their security controls. We generally require third parties to maintain security controls, notify us promptly of any data breach or cybersecurity incident that may impact our data, and provide written assurance of corrective actions; and

5. Engaging and utilizing a comprehensive suite of security solutions, including enterprise mobility management, endpoint protection, secure file transfer, and security information and event management to monitor and actively respond to cybersecurity threats. These solutions work together to secure our endpoints, protect against malware, ensure the safe transfer of files, and provide our cybersecurity team with the functionality to build alerts on specific use cases that are important and unique to our business.

Cybersecurity Governance

Our Board oversees cybersecurity risk as part of its overall risk oversight function. We utilize resources from AULT to act as our information technology department (the “IT Department”), which functions as our Information Security Advisory Team. The IT Department is responsible for managing our information security program and implementing cybersecurity risk management practices.

The IT Department collaborates with various stakeholders across the organization to identify, assess, and mitigate cybersecurity risks. They regularly monitor and adapt our information security program to address the evolving threat landscape.

In the event of a cybersecurity incident, the IT Department promptly reports the matter to the Chief Financial Officer. The Chief Financial Officer is responsible for assessing the severity and potential impact of the incident and determining the appropriate course of action. The Chief Financial Officer keeps the Board informed of significant cybersecurity incidents and provides updates on the overall status of our cybersecurity program as needed.

This governance structure ensures that cybersecurity risks are effectively managed by the IT Department, with oversight from the Chief Financial Officer and the Board. It maintains clear lines of communication and accountability, enabling timely decision-making and response to cybersecurity matters.

During fiscal 2024, we did not identify any cybersecurity threats that have materially affected or are reasonably likely to materially affect our business strategy, results of operations or financial condition. However, despite our efforts, we may not successfully eliminate all risks from cybersecurity threats and can provide no assurance that undetected cybersecurity incidents have not occurred.

ITEM 2. PROPERTIES

Our executive office is currently located at 3480 Peachtree Road NE, Second Floor, Suite 103, Atlanta, GA 30326, where we utilize shared labs and extensive research resources. Our accounting and finance office is located in Orange County, California utilizing approximately 200 square feet of shared office space within the offices of AULT, a related party. Our legal office is located in New York, NY utilizing shared office space within the offices of AULT. We currently do not pay rent for our Orange County, California or New York, NY office spaces. We believe our present space is adequate for our current operations.

ITEM 3. LEGAL PROCEEDINGS

We are subject to various claims and legal actions arising in the ordinary course of our business. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence of any such litigation could harm our business, results of operations and financial condition. Results of actual and potential litigation are inherently uncertain. An unfavorable result in a legal proceeding could adversely affect our reputation, financial condition and operating results. There are no legal proceedings or arbitration proceedings currently pending against our company.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on The NASDAQ Capital Market under the symbol "ALZN". Effective July 16, 2024, we effected a one-for-ten reverse stock split of our common stock

Holders of Record

As of July 29, 2024, there were approximately 67 stockholders of record of our common stock. The actual number of stockholders is greater than this number of record holders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust or by other entities.

Dividend Policy

We have never declared or paid any cash dividends on our capital stock, and we do not currently intend to pay any cash dividends on our capital stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to support operations and to finance the growth and development of our business. Any future determination to pay dividends will be made at the discretion of our Board subject to applicable laws and will depend upon, among other factors, our results of operations, financial condition, contractual restrictions and capital requirements. Our future ability to pay cash dividends on our capital stock may be limited by any future debt instruments or preferred securities.

Equity Compensation Information

The information required by this item regarding equity compensation plans is incorporated by reference to the information set forth in Item 12 of this Annual Report on Form 10-K.

Recent Sales of Unregistered Securities

None.

Purchases of Equity Securities by the Issuer and Affiliated Purchasers

None.

ITEM 6. [RESERVED]

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of our operations together with our financial statements and the notes thereto appearing elsewhere in this Annual Report. This discussion contains forward-looking statements reflecting our current expectations, whose actual outcomes involve risks and uncertainties. Actual results and the timing of events may differ materially from those stated in or implied by these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Risk Factors" and "Special Note Regarding Forward-Looking Statements," and elsewhere in this Annual Report.

Overview

We were incorporated on February 26, 2016, as Alzamend Neuro, Inc. under the laws of the State of Delaware. We were formed to acquire and commercialize patented intellectual property and know-how to prevent, treat and potentially cure the crippling and deadly Alzheimer's. With our two product candidates, we aim to bring treatment or cures not only for Alzheimer's, but also, bipolar disorder ("BD"), major depressive disorder ("MDD") and post-traumatic stress disorder ("PTSD"). Existing Alzheimer's treatments only temporarily relieve symptoms but do not, to our knowledge, slow or halt the underlying worsening of the disease. We have developed a novel approach to combat Alzheimer's through immunotherapy.

Critical Accounting Policies and Estimates

***Research and Development Expenses*.** Research and development costs are expensed as incurred. Research and development costs consist of scientific consulting fees and lab supplies, as well as fees paid to other entities that conduct certain research and development activities on behalf of our company.

We have acquired and may continue to acquire the rights to develop and commercialize new product candidates from third parties. The upfront payments to acquire license, product or rights, as well as any future milestone payments, are immediately recognized as research and development expense provided that there is no alternative future use of the rights in other research and development projects.

Stock-Based Compensation. We maintain a stock-based compensation plan as a long-term incentive for employees, non-employee directors and consultants. The plan allows for the issuance of incentive stock options, non-qualified stock options, restricted stock units, and other forms of equity awards.

We recognize stock-based compensation expense for stock options on a straight-line basis over the requisite service period and account for forfeitures as they occur. Our stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model. To the extent any stock option grants are made subject to the achievement of a performance-based milestone, management evaluates when the achievement of any such performance-based milestone is probable based on the relative satisfaction of the performance conditions as of the reporting date.

The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally require significant judgment. These assumptions include:

- ***Risk-Free Interest Rate.*** The risk-free interest rate is based on the U.S. Treasury zero coupon issues in effect at the time of grant for periods corresponding with the expected term of the option;

- ***Expected Volatility.*** Because we do not have an extensive trading history for our common stock, the expected volatility was estimated based on the average volatility for comparable publicly traded life sciences companies over a period equal to the expected term of the stock option grants. Comparable companies were chosen based on the similar size, stage in life cycle or area of specialty. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own stock price becomes available;

- ***Expected Term.*** The expected term represents the period that the stock-based awards are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term), as we do not have sufficient historical data to use any other method to estimate expected term; and

- ***Expected Dividend Yield.*** We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.

Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and we use significantly different assumptions or estimates, our stock-based compensation could be materially different.

Income Taxes. We recognize deferred income taxes for the future tax consequences attributed to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating loss and tax credit carryforwards. Deferred tax assets are reduced by a valuation allowance to the extent management concludes it is more likely than not that the assets will not be realized. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the fiscal years in which those temporary differences are expected to be recovered or settled.

In accordance with Internal Revenue Code §382 (“IRC §382”), the future deductibility of our net operating losses (“NOLs”) may be subject to an annual limitation in the event of a change in control as defined by applicable regulations. We have yet to complete a formal study to confirm NOLs are not limited in utilization per IRC §382 and may reduce applicable deferred tax assets upon completion of such a study, in future periods.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. We had no uncertain tax positions as of April 30, 2024.

Preferred Stock Classification. We analyze the terms of our preferred stock using Accounting Standards Codification (“ASC”) 480, *Distinguishing Liabilities from Equity*, to determine whether our preferred stock should be classified as a liability or equity, and if classified as equity, permanent or temporary. Common criteria we consider are redemption provisions, conversion options, cumulative of mandatory fixed dividends, discretionary dividends based on earning, voting rights and collateral requirements.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act of 2012 (the “JOBS Act”). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act, until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an emerging growth company or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Plan of Operations

We intend to develop and commercialize therapeutics that are better than existing treatments and have the potential to significantly improve the lives of individuals afflicted by Alzheimer’s, BD, MDD and PTSD. To achieve these goals, we are pursuing the following key business strategies:

- Advance clinical development of AL001 for Alzheimer’s, BD, MDD and PTSD treatment;

- Advance clinical development of ALZN002 for Alzheimer’s treatment;

- Expand our pipeline of pharmaceuticals to include additional indications for AL001 and delivery methods;

- Focus on translational and functional endpoints to efficiently develop product candidates; and

- Optimize the value of AL001 and ALZN002 in major markets.

Our pipeline consists of two novel therapeutic drug candidates:

- AL001 - A patented ionic cocrystal technology delivering a therapeutic combination of lithium, salicylate and proline through three royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc., as licensor (the “Licensor”); and

- ALZN002 - A patented method using a mutant peptide sensitized cell as a cell-based therapeutic vaccine that seeks to restore the ability of a patient’s immunological system to combat Alzheimer’s through a royalty-bearing exclusive worldwide license from the Licensor.

Our most advanced product candidate (lead product) licensed and in clinical development in humans is AL001, an ionic cocrystal of lithium for the treatment of Alzheimer’s, BD, MDD and PTSD. Based on our preclinical data involving mice models, AL001 treatment prevented cognitive deficits, depression and irritability and is superior in improving associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of this lithium formulation for the treatment of Alzheimer’s, BD, MDD and PTSD in humans. Lithium has been marketed for more

than 35 years and human toxicology regarding lithium use has been well characterized, potentially mitigating the regulatory burden for safety data.

On May 5, 2022, we initiated a multiple-dose, steady-state, double-blind, ascending dose safety, tolerability, pharmacokinetic clinical trial of AL001 in patients with mild to moderate Alzheimer's and healthy subjects. We completed the Phase IIA clinical trial in March 2023 and announced positive topline data in June 2023.

We announced that we successfully identified a maximum tolerated dose ("MTD") for development of AL001 from a multiple-ascending dose study as assessed by an independent safety review committee. This dose, providing lithium at a lithium carbonate equivalent dose of 240 mg 3-times daily ("TID"), is designed to be unlikely to require lithium therapeutic drug monitoring ("TDM"). Also, this MTD is risk mitigated for the purpose of treating fragile populations, such as Alzheimer's patients.

Lithium is a commonly prescribed drug for manic episodes in BP type 1 as well as maintenance therapy of BP in patients with a history of manic episodes. Lithium is also prescribed off-label for MDD, BP and treatment of PTSD, among other disorders. Lithium was the first mood stabilizer approved by the FDA and is still a first-line treatment option (considered the "gold standard") but is underutilized perhaps because of the need for TDM. Lithium was the first drug that required TDM by regulatory authorities in product labelling because the effective and safe range of therapeutic drug blood concentrations is narrow and well defined for treatment of BP when using lithium salts. Excursions above this range can be toxic, and below can impair effectiveness.

Based on the results from our Phase IIA MAD study, we plan to initiate two safety and efficacy clinical trials in subjects with mild to moderate dementia of the Alzheimer's type. Additionally, we are investigating the potential of AL001 for patients suffering from BD, MDD and PTSD, and submitted IND applications to the FDA for these indications. The IND for BD was submitted in August 2023 and we received a "study may proceed" letter from the FDA in September 2023. The IND for MDD was submitted in October 2023 and we received a "study may proceed" letter from the FDA in November 2023. The IND for PTSD was submitted in November 2023 and we received a "study may proceed" from the FDA in December 2023. We intend to initiate clinical trials in 2025 at this MTD to determine relative increased lithium levels in the brain compared to a marketed lithium salt for Alzheimer's, BD, MDD and PTSD, based on published mouse studies that predict that lithium can be given at lower doses for equivalent therapeutic benefit when treating with AL001. For example, the goal is to replace a 300 mg TID lithium carbonate dose for treatment of BD with a 240 mg TID AL001 lithium equivalent, which represents a daily decrease of 20% of lithium given to a patient.

On September 28, 2022, we submitted an IND application to the FDA for ALZN002 and received a "study may proceed" letter on October 31, 2022. The product candidate is an immunotherapy vaccine designed to treat mild to moderate dementia of the Alzheimer's type. ALZN002 is a proprietary "active" immunotherapy product, which means it is produced by each patient's immune system. It consists of autologous DCs that are activated white blood cells taken from each individual patient so that they can be engineered outside of the body to attack Alzheimer's-related amyloid-beta proteins. These DCs are pulsed with a novel amyloid-beta peptide (E22W) designed to bolster the ability of the patient's immune system to combat Alzheimer's; the goal being to foster tolerance to treatment for safety purposes while stimulating the immune system to reduce the brain's beta-amyloid protein burden, resulting in reduced Alzheimer's signs and symptoms. Compared to passive immunization treatment approaches that use foreign blood products (such as monoclonal antibodies), active immunization with ALZN002 is anticipated to offer a more robust and long-lasting effect on the clearance of amyloid. This could provide a safer approach due to its reliance on autologous immune components, using each individual patient's own white blood cells rather than foreign cells and/or blood products.

On April 3, 2023, we announced the initiation of a Phase I/IIA clinical trial for ALZN002 to treat mild to moderate dementia of the Alzheimer's type. The purpose of this trial is to assess the safety, tolerability, and efficacy of multiple ascending doses of ALZN002 compared with that of a placebo in 20-30 subjects with mild to moderate morbidity. The primary goal of this clinical trial is to determine an appropriate dose of ALZN002 for treatment of patients with Alzheimer's in a larger Phase IIB efficacy and safety clinical trial. On February 13, 2024, we received notice from the company we engaged as our contract research organization ("CRO"), Biorasi, LLC ("Biorasi") that Biorasi was terminating our contract with them. We are currently pursuing the engagement of a replacement CRO.

The continuation of our current plan of operations with respect to completing our IND applications and conducting the series of human clinical trials for each of our therapeutics requires us to raise additional capital to fund our operations.

Because our working capital requirements depend upon numerous factors, including the progress of our preclinical and clinical testing, timing and cost of obtaining regulatory approvals, changes in levels of resources that we devote to the development of manufacturing and marketing capabilities, competitive and technological advances, status of competitors, and our ability to establish collaborative arrangements with other organizations, we will require additional financing to fund future operations.

Results of Operations

Results of Operations for the Year Ended April 30, 2024 Compared to Year Ended April 30, 2023

The following table summarizes the results of our operations for the years ended April 30, 2024 and 2023:

	For the Year Ended April 30,			
	2024	2023	$ Change	% Change
OPERATING EXPENSES				
Research and development	$ 6,455,107	$ 7,445,857	$ (990,750)	-13%
General and administrative	3,482,538	7,424,609	(3,942,071)	-53%
Total operating expenses	9,937,645	14,870,466	(4,932,821)	-33%
Loss from operations	(9,937,645)	(14,870,466)	4,932,821	-33%
OTHER EXPENSE, NET				
Interest expense	(10,101)	(7,701)	(2,400)	31%
Total other expense, net	(10,101)	(7,701)	(2,400)	31%
NET LOSS	$ (9,947,746)	$ (14,878,167)	$ 4,930,421	-33%
Basic and diluted net loss per common share	$ (14.70)	$ (22.89)	$ 8.19	*
Basic and diluted weighted average common shares outstanding	676,565	650,126		*

* Not meaningful

Revenue

We currently have only two product candidates, AL001 and ALZN002. These products are in the clinical stage of development and will require extensive clinical study, review and evaluation, regulatory review and approval, significant marketing efforts and substantial investment before either or both of them, and any respective successors, will provide us with any revenue. We did not generate any revenues during the years ended April 30, 2024 and 2023, and we do not anticipate that we will generate revenue for the foreseeable future.

Research and Development Expenses

Research and development expenses for the years ended April 30, 2024 and 2023 were $6.5 million and $7.4 million, respectively. As reflected in the table below, research and development expenses primarily consisted of professional fees, clinical trial fees, stock-based compensation expense, as well as other research and development expenses:

	For the Year Ended April 30,			
	2024	2023	$ Change	% Change
Professional fees	$ 2,898,402	$ 4,617,816	$ (1,719,414)	-37%
Clinical trial fees	3,246,578	2,465,437	781,141	32%
Stock-based compensation expense	213,905	(42,589)	256,494	602%
Other research and development expenses	96,222	405,193	(308,971)	-76%
Total research and development expenses	$ 6,455,107	$ 7,445,857	$ (990,750)	-13%

Professional Fees

During the years ended April 30, 2024 and 2023, we incurred professional fees of $2.9 million and $4.6 million, respectively, which were primarily comprised of professional fees attributed to various types of scientific services, including FDA consulting services. The decrease relates to lower professional fees incurred related to the preparation for the clinical trial for ALZN002 during the year ended April 30, 2024, compared to professional fees incurred for the Phase IIA clinical trial for AL001 during the year ended April 30, 2023.

Clinical Trial Fees

During the years ended April 30, 2024 and 2023, we incurred clinical trial fees of $3.2 million and $2.5 million, respectively, Clinical trial fees for the year ended April 30, 2024, consisted of $1.9 million for our Phase IIA clinical trial for AL001 and $1.3 million for our Phase IIA clinical trial for ALZN002. Clinical trial fees for the year ended April 30, 2023 were for our Phase I clinical trial for AL001.

Stock-Based Compensation Expense

During the years ended April 30, 2024 and 2023, we incurred $214,000 and $(43,000), respectively, in research and development stock-based compensation expense related to stock option grants to consultants. The increase in research and development stock-based compensation expense for the year ended April 30, 2024 was a result of the vesting of performance stock options grants.

Other Research and Development Expenses

During the years ended April 30, 2024 and 2023, we incurred other fees of $96,000 and $405,000, respectively, which were primarily comprised of scientific materials required for our clinical trials.

General and Administrative Expenses

General and administrative expenses for the years ended April 30, 2024 and 2023 were $3.5 million and $7.4 million, respectively. As reflected in the table below, general and administrative expenses primarily consisted of the following expense categories: stock-based compensation expense; salary and benefits; professional fees; marketing fees; insurance; travel and entertainment; as well as Board fees. For the years ended April 30, 2024 and 2023, the remaining general and administrative expenses of $381,000 and $514,000, respectively, primarily consisted of payments for advertising and promotion, transfer agent fees, travel, and other office expenses, none of which is significant individually.

	For the Year Ended April 30,			
	2024	2023	$ Change	% Change
Salary and benefits	$ 836,046	$ 1,042,860	$ (206,814)	-20%
Stock-based compensation expense	741,728	3,625,214	(2,883,486)	-80%
Professional fees	735,915	762,396	(26,481)	-3%
Insurance	381,737	587,427	(205,690)	-35%
Marketing fees	247,334	742,601	(495,267)	-67%
Board fees	158,333	150,000	8,333	6%
Other general and administrative expenses	381,446	514,111	(132,665)	-26%
Total general and administrative expenses	$ 3,482,538	$ 7,424,609	$ (3,942,071)	-53%

Salary and Benefits

During the years ended April 30, 2024 and 2023, we incurred $836,000 and $1.0 million, respectively, in employee-related expenses. As of April 30, 2024, we had four full-time and three part-time employees. The decrease in salary and benefits expense was a result of lower bonuses earned during the year ended April 30, 2024.

Stock-based Compensation Expense

During the years ended April 30, 2024 and 2023, we incurred general and administrative stock-based compensation expense of $741,000 and $3.6 million, respectively, related to stock option grants to executives, employees and consultants. The decrease in stock-based compensation expense for the year ended April 30, 2024 was a result of fewer stock options vesting during the period compared to the prior year period.

Professional Fees

During the years ended April 30, 2024 and 2023, we incurred professional fees of $736,000 and $762,000, respectively. During the year ended April 30, 2024, we incurred $341,000 in audit and tax fees, $192,000 in investor relations, $104,000 in legal fees, $33,000 in related party consulting, $28,000 in Sarbanes-Oxley compliance fees and $38,000 in other professional fees. During the year ended April 30, 2023, we incurred $189,000 in

Sarbanes-Oxley compliance fees, $187,000 in connection with a consulting agreement, $187,000 in audit and tax fees, $126,000 in legal fees, $50,000 in related party consulting and $23,000 in other professional fees.

Insurance Expense

During the years ended April 30, 2024 and 2023, we incurred insurance expense of $382,000 and $587,000, respectively, which was primarily directors and officers insurance.

Marketing Fees

During the years ended April 30, 2024 and 2023, we incurred marketing fees of $247,000 and $743,000, respectively, which was primarily expenses related to the marketing and brand development agreement with AULT.

Current and Deferred Income Taxes

As of April 30, 2024 and 2023, we had deferred tax assets totaling $15.8 million and $10.8 million, respectively. The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management believes it is more likely than not that some or all of the deferred tax assets will not be realized. Accordingly, we have established a 100% valuation allowance. As a result of the full valuation allowance, we did not record an income tax benefit for the years ended April 30, 2024 and 2023.

Liquidity and Capital Resources

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred recurring net losses and operations have not provided sufficient cash flows. We believe that we will continue to incur operating and net losses each quarter until at least the time we begin significant deliveries of our products. We believe our current cash on hand is insufficient to fund our planned operations through one year after the date the financial statements are issued. These factors create substantial doubt about our ability to continue as a going concern for at least one year after the date that our audited financial statements are issued.

Our inability to continue as a going concern could have a negative impact on our company, including our ability to obtain needed financing. We intend to finance our future development activities and our working capital needs largely through the sale of equity securities with some additional funding from other sources, including debt financing, until such time as funds provided by operations are sufficient to fund working capital requirements. Our financial statements do not include any adjustments relating to the recoverability and classification of recorded assets, or the amounts and classifications of liabilities that might be necessary should we be unable to continue as a going concern. As of April 30, 2024, we had cash of $376,000 and an accumulated deficit of $54.0 million. We have incurred recurring losses and reported losses for the year ended April 30, 2024 totaling $9.9 million. In the past, we have financed our operations principally through sales of equity securities and debt instruments.

We will need to obtain substantial additional funding in the future for our clinical development activities and continuing operations. If we are unable to raise capital when needed or on favorable terms, we would be forced to delay, reduce, or eliminate our research and development programs or future commercialization efforts. As previously disclosed, we had anticipated beginning Phase II clinical trials for AL001 additional indications in the first quarter of calendar 2024. Due to the Company's inability to obtain significant additional financing, we have been unable to initiate those clinical trials and reduce the working capital deficiency. Our future capital requirements will depend on many factors, including:

- successful enrollment in and completion of clinical trials;
- our ability to establish agreements with third-party manufacturers for clinical supply for our clinical trials and, if our product candidates are approved, commercial manufacturing;
- our ability to maintain our current research and development programs and establish new research and development programs;
- addition and retention of key research and development personnel;
- our efforts to enhance operational, financial, and information management systems, and hire additional personnel, including personnel to support development of our product candidates;
- negotiating favorable terms in any collaboration, licensing, or other arrangements into which we may enter and performing our obligations in such collaborations;
- the timing and amount of milestone and other payments we may receive under our collaboration arrangements;

- our eventual commercialization plans for our product candidates;
- the costs involved in prosecuting, defending, and enforcing patent claims and other intellectual property claims; and
- the costs and timing of regulatory approvals.

A change in the outcome of any of these or other variables with respect to the development of any of our product candidates could significantly change the costs and timing associated with the development of that product candidate. Furthermore, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

On September 8, 2023, we entered into an At-the-Market Issuance Sales Agreement with Ascendiant Capital Markets, LLC, as sales agent to sell shares of our common stock, having an aggregate offering price of up to approximately $9.8 million from time to time, through an "at the market offering" (the "ATM Offering") as defined in Rule 415 under the Securities Act. On September 8, 2023, we filed a prospectus supplement with the SEC relating to the offer and sale of up to approximately $9.8 million in shares of common stock in the ATM Offering.

During the year ended April 30, 2024, we sold an aggregate of 107,682 shares of common stock pursuant to the ATM Offering for proceeds of

$1.3 million. On May 6, 2024, we terminated our ATM Offering.

Series B Preferred Financing

On January 31, 2024, we entered into a securities purchase agreement with Ault Lending ("AL SPA") whereby Ault Lending may purchase of up to 6,000 shares of series B convertible preferred stock ("Series B Convertible Preferred Stock") and warrants to purchase shares up to 600,000 shares of our common stock. The AL SPA provides that Ault Lending may purchase up to $6 million of Series B Convertible Preferred Stock in one or more closings. Ault Lending has the right to purchase up to $2 million of Series B Convertible Preferred Stock, on or before March 31, 2024, and the right to purchase up to $4 million of Series B Convertible Preferred Stock after March 31, 2024, but on or before March 31, 2025 (the "Termination Date"). The Agreement will automatically terminate if the final closing has not occurred prior to the Termination Date.

On January 31, 2024, we sold 1,220 shares of Series B Convertible Preferred Stock and warrants to purchase 122,000 shares of common stock with an exercise price of $12.00, for a total purchase price of $1.22 million. The purchase price was paid by the cancellation of $1.15 million of cash advances made by Ault Lending to us between November 9, 2023 and January 31, 2024 and a subscription receivable of $70,000. On March 26, 2024, we sold 780 shares of Series B Convertible Preferred Stock and warrants to purchase 78,000 shares of common stock with an exercise price of $12.00, for a total purchase price of $780,000. On April 29, 2024, we sold 100 shares of Series B Convertible Preferred Stock and warrants to purchase 10,000 shares of common stock with an exercise price of $12.00, for a total purchase price of $100,000.

The Series B Convertible Preferred Stock has a stated value of $1,000 per share ("Series B Stated Value") and does not accrue dividends. Each share of Series B Convertible Preferred Stock is convertible into a number of shares of common stock determined by dividing the Series B Stated Value by $10.00 (the "Series B Conversion Price"). The Series B Conversion Price is subject to adjustment in the event of an issuance of common stock at a price per share lower than the Series B Conversion Price then in effect, as well as upon customary stock splits, stock dividends, combinations or similar events. The holders of the Series B Convertible Preferred Stock are entitled to vote with the common stock as a single class on an as-converted basis, subject to applicable law provisions of the Delaware General Corporation Law and Nasdaq, provided however, that for purposes of complying with Nasdaq regulations, the conversion price, for purposes of determining the number of votes the holder of Series B Convertible Preferred Stock is entitled to cast, shall not be lower than $8.73 (the "Voting Floor Price"), which represents the closing sale price of the common stock on the trading day immediately prior to the date of execution of the AL SPA. The Voting Floor Price shall be adjusted for stock dividends, stock splits, stock combinations and other similar transactions.

The warrants have an exercise price of $12.00 (the "Series B Exercise Price") and become exercisable on the first business day after the six-month anniversary of issuance (the "Series B Initial Exercise Date") and have a five-year term, expiring on the fifth anniversary of the Series B Initial Exercise Date. The Series B Exercise Price is subject to adjustment in the event of an issuance of common stock at a price per share lower than the Series B Exercise Price then in effect, as well as upon customary stock splits, stock dividends, combinations or similar events.

For the period ended January 31, 2024, we recorded the Series B Convertible Preferred Stock as mezzanine equity and the warrant as a liability. On March 21, 2024, we amended our Amended and Restated Certificate of Designations for our Series B Convertible Preferred Stock to remove certain change of control language that could be interpreted to require either debt or equity classification of the Series B Convertible Preferred Stock. As a result, we classified both the Series B Convertible Preferred Stock and warrant as equity for the period ended April 30, 2024.

Series A Preferred Financing

On May 8, 2024, we and Orchid Finance, LLC ("Orchid") , entered into a securities purchase agreement (the "Orchid SPA") for the purchase of up to 2,500 shares of Series A Convertible Preferred Stock ("Series A Convertible Preferred Stock") and warrants to purchase shares up to 2,500,000 shares of common stock in several tranche closings.

On May 10, 2024, we sold 100 shares of Series A Convertible Preferred Stock and warrants to purchase 80,000 shares of common stock with an exercise price of $12.50, for a total purchase price of $1.0 million. The purchase price was paid by the surrender and cancellation of a term note issued by us to Orchid of $311,356, consisting of $310,000 of principal and $1,356 of accrued and unpaid interest, $100,000 discount and net cash of $588,644. On June 25, 2024, we sold 150 shares of Series A Convertible Preferred Stock and warrants to purchase 120,000 shares of common stock with an exercise price of $12.50, for a total purchase price of $1.5 million. The purchase price was paid in cash.

Pursuant to the Orchid SPA, Orchid has agreed to purchase the remaining 2,250 Preferred Shares based on our achievement of the milestones set forth below (the "Milestones"):

- 250 Preferred Shares, for $2,500,000, within 30 days of the effectiveness of a resale registration statement (the "Registration Statement");
- 200 Preferred Shares, for $2,000,000, within 60 days of the effectiveness of the Registration Statement and the execution of a partnership agreement with a nationally renowned research facility for a clinical trial (the "Fourth Tranche"); and
- 100 Preferred Shares, for $1,000,000, on each monthly anniversary of the effectiveness of the Registration Statement until all remaining 1,800 Preferred Shares have been sold (each, a "Final Tranche").

Notwithstanding the foregoing Milestones, Orchid has the ability to invest any amount in its sole discretion in advance of the dates that the foregoing Milestones shall have been met. In the event that the average closing price of the common stock during the three trading days preceding the date of a tranche closing shall not be equal to or greater than $2.50 a share (the "Floor Price"), then the applicable closing shall be delayed until such time as the price meets the required threshold. We agreed to pay Ault Lending an origination fee of five percent (5%) of the total gross proceeds we receive from Orchid upon each purchase of Series A Convertible Preferred Stock. We also agreed to pay Orchid a fee of $100,000 upon the first closing, which occurred on May 10, 2024, the Fourth Tranche and the third, eighth and thirteenth closings constituting parts of the Final Tranche.

The Registration Statement registering for resale the shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock and exercise of the warrants was declared effective on July 9, 2024. In addition, we agreed to use our best efforts to hold a special meeting of our stockholders within 90 days of the execution date of the Orchid SPA for purposes of seeking stockholder approval of the issuance of all the shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock and the exercise of the warrants in excess of the "Nasdaq Limit", which is 19.99% of our shares of common stock issued and outstanding on the execution date of the Orchid SPA. We held a special meeting of stockholders on July 8, 2024, at which time, the stockholders approved the issuance of all the shares of common stock issuable upon conversion of the Series A Convertible Preferred Stock and the exercise of the warrants in excess of the "Nasdaq Limit".

The Series A Convertible Preferred Stock has a stated value of $10,000 per share ("Series A Stated Value") and accrues dividends at the rate of 15% per annum, payable quarterly in arrears in cash or paid-in-kind shares, in Orchid's sole discretion. Each share of Series A Convertible Preferred Stock is convertible into a number of shares of common stock determined by dividing the Series A Stated Value by (y) the greater of (i) the Floor Price and (ii) the lesser of (A) $15.00 and (B) 80% of the lowest closing price of our common stock during the three trading days immediately prior to the date of

conversion into conversion shares (the "Series A Conversion Price"). The Series A Conversion Price is subject to adjustment in the event of an issuance of common stock at a price per share lower than the Series A Conversion Price then in effect, as well as upon customary stock splits, stock dividends, combinations or similar events. The holders of the Series A Convertible Preferred Stock are entitled to vote with the common stock as a single class on an as-converted basis, subject to applicable law provisions of the Delaware General Corporation Law and Nasdaq, provided however, that for purposes of complying with Nasdaq regulations, the conversion price, for purposes of determining the number of votes the holder of Series B Convertible Preferred Stock is entitled to cast, shall not be lower than $5.63 (the "Series A Voting Floor Price"), which represents the closing sale price of the common stock on the trading day immediately prior to the date of execution of the Orchid SPA. The Series A Voting Floor Price shall be adjusted for stock dividends, stock splits, stock combinations and other similar transactions.

The warrants have an exercise price of $12.50 (the "Series A Exercise Price") and are exercisable upon issuance and have a five-year term, expiring on the fifth anniversary of issuance. The Series A Exercise Price is subject to adjustment in the event of an issuance of common stock at a price per share lower than the Series A Exercise Price then in effect, as well as upon customary stock splits, stock dividends, combinations or similar events. The warrants are exercisable on a cashless basis in the event that there is not then an effective resale registration statement for the common stock issuable upon exercise of the warrants.

Cash Flows

The following table summarizes our cash flows for the years ended April 30, 2024 and 2023:

	For the Year Ended April 30,	
	2024	2023
Net cash provided by (used in):		
Operating activities	$ (8,269,993)	$ (8,923,152)
Investing activities	(147,243)	-
Financing activities	3,652,425	200
Net decrease in cash and cash equivalents	$ (4,764,811)	$ (8,922,952)

Operating Activities

During the year ended April 30, 2024, net cash used in operating activities was $8.3 million. This consisted primarily of a net loss of $9.9 million, partially offset by non-cash charges of $956,000 in stock-based compensation expense and an increase in our net operating assets and liabilities of $671,000. The increase in our net operating assets and liabilities was primarily due to an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses.

During the year ended April 30, 2023, net cash used in operating activities was $8.9 million. This consisted primarily of a net loss of $14.9 million, partially offset by non-cash charges of $3.6 million in stock-based compensation expense and an increase in our net operating assets and liabilities of $2.3 million. The increase in our net operating assets and liabilities was primarily due to an increase in accounts payable and accrued liabilities and a decrease in prepaid expenses – related party.

Investing Activities

During the year ended April 30, 2024, net cash used in investing activities was $147,000, from the purchase of equipment and machinery to be used in our ALZN002 Phase I/IIA clinical trial.

Financing Activities

During the year ended April 30, 2024, net cash provided by financing activities was $2.1 million from the sale of convertible preferred stock to Ault Lending, a related party, $1.3 million from proceeds from the ATM Offering and $300,000 from a promissory note.

During the year ended April 30, 2023, net cash provided by financing activities was $200 from the exercise of stock options.

Contractual Obligations

On July 2, 2018, we entered into two Standard Exclusive License Agreements with Sublicensing Terms for AL001 with the Licensor and its affiliate, the University of South Florida (the "AL001 Licenses"), pursuant to which the Licensor granted us a royalty bearing exclusive worldwide licenses limited to the field of Alzheimer's, under United States Patent Nos. (i) 9,840,521, entitled "Organic Anion Lithium Ionic Cocrystal Compounds and Compositions", filed September 24, 2015 and granted December 12, 2017, and (ii) 9,603,869, entitled "Lithium Co-Crystals for Treatment of Neuropsychiatric Disorders", filed May 21, 2016 and granted March 28, 2017. On February 1, 2019, we entered into the First Amendments to the AL001 Licenses, on March 30, 2021, we entered into the Second Amendments to the AL001 Licenses and on June 8, 2023, we entered into the Third Amendments to the AL001 Licenses (collectively, the "AL001 License Agreements"). The Third Amendments to the AL001 Licenses modified the timing of the payments for the license fees.

The AL001 License Agreements require that we pay combined royalty payments of 4.5% on net sales of products developed from the licensed technology for AL001. We have already paid an initial license fee of $200,000 for AL001. As an additional licensing fee for the license of the AL001 technologies, the Licensor received 14,853 shares of our common stock. Minimum royalties for AL001 License Agreements are $40,000 on the first anniversary of the first commercial sale, $80,000 on the second anniversary of the first commercial sale and $100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the AL001 License Agreements.

On May 1, 2016, we entered into a Standard Exclusive License Agreement with Sublicensing Terms for ALZN002 with the Licensor (the "ALZN002 License"), pursuant to which the Licensor granted us a royalty bearing exclusive worldwide license limited to the field of Alzheimer's Immunotherapy and Diagnostics, under United States Patent No. 8,188,046, entitled "Amyloid Beta Peptides and Methods of Use", filed April 7, 2009 and granted May 29, 2012. On August 18, 2017, we entered into the First Amendment to the ALZN002 License, on May 7, 2018, we entered into the Second Amendment to the ALZN002 License, on January 31, 2019, we entered into the Third Amendment to the ALZN002 License, on January 24, 2020, we entered into the Fourth Amendment to the ALZN002 License, on March 30, 2021, we entered into the Fifth Amendment to the ALZN002 License, on April 17, 2023, we entered into the Sixth Amendment to the ALZN002 License and on December 11, 2023, we entered into the Seventh Amendment to the ALZN002 License (collectively, the "ALZN002 License Agreement"). The Seventh Amendment to the ALZN002 License modified the timing of the payments for the license fees.

The ALZN002 License Agreement requires us to pay royalty payments of 4% on net sales of products developed from the licensed technology for ALZN002. We have already paid an initial license fee of $200,000 for ALZN002. As an additional licensing fee for the license of ALZN002, the Licensor received 24,012 shares of our common stock. Minimum royalties for ALZN002 are $20,000 on the first anniversary of the first commercial sale, $40,000 on the second anniversary of the first commercial sale and $50,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the ALZN002 License Agreement.

On November 19, 2019, we entered into two Standard Exclusive License Agreements with Sublicensing Terms for two additional indications of AL001 with the Licensor (the "November AL001 License"), pursuant to which the Licensor granted us a royalty bearing exclusive worldwide licenses limited to the fields of (i) neurodegenerative diseases excluding Alzheimer's and (ii) psychiatric diseases and disorders. On March 30, 2021, we entered into the First Amendments to the November AL001 License and on April 17, 2023, we entered into the Second Amendments to the November AL001 License (collectively, the "November AL001 License Agreements"). The Second Amendments to the November AL001 License modified the timing of the payments for the license fees.

The November AL001 License Agreements require us to pay royalty payments of 3% on net sales of products developed from the licensed technology for AL001 in those fields. We paid an initial license fee of $20,000 for the additional indications. Minimum royalties for November AL001 License Agreements are $40,000 on the first anniversary of the first commercial sale, $80,000 on the second anniversary of the first commercial sale and $100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the November AL001 License Agreements.

These license agreements have an indefinite term that continue until the later of the date no licensed patent under the applicable agreement remains a pending application or enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, or the date on which the licensee's obligations to pay royalties expire under the applicable license agreement. Under our various license agreements, if we fail to meet a milestone by its specified date, Licensor may terminate the license agreement. The Licensor was also granted a preemptive right to acquire such shares or other equity securities that may be issued from time to time by us while the Licensor remains the owner of any equity securities of our company.

Additionally, we are required to pay milestone payments on the due dates to the Licensor for the license of the AL001 technologies and for the ALZN002 technology, as follows:

Original AL001 Licenses:

Payment	Due Date	Event
$ 50,000*	Completed September 2019	Pre-IND meeting
$ 65,000*	Completed June 2021	IND application filing
$ 190,000*	Completed December 2021	Upon first dosing of patient in a clinical trial
$ 500,000*	Completed March 2022	Upon completion of first clinical trial
$ 1,250,000	March 2025	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	8 years from the effective date of the agreement	Upon FDA NDA approval

* Milestone met and completed

ALZN002 License:

Payment	Due Date
$ 50,000*	Upon IND application - completed January 2022
$ 50,000	Upon first dosing of patient in first Phase I clinical trial
$ 500,000	Upon completion of first Phase IIB clinical trial
$ 1,000,000	Upon first patient treated in a Phase III clinical trial
$10,000,000	Upon first commercial sale

* Milestone met and completed

Additional AL001 Licenses:

Payment	Due Date	Event
$ 2,000,000	March 2026	Upon first patient treated in a Phase III clinical trial
$ 16,000,000	August 1, 2029	First commercial sale

Recent Accounting Standards

For information about recent accounting pronouncements that may impact our financial statements, please refer to Note 3 of Notes to Financial Statements under the heading "Recent Accounting Standards."

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Because we are a smaller reporting company, this section is not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements required by this Item 8 are included in this Annual Report following Item 16 hereof. As a smaller reporting company, we are not required to provide supplementary financial information.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our periodic and current reports that we file with the SEC is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable and not absolute assurance of achieving the desired control objectives. In reaching a reasonable level of assurance, management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. In addition, the design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, controls may become inadequate because of changes in conditions, or the degree of compliance with policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

As of April 30, 2024, we carried out an evaluation, under the supervision of, and with the participation of, our management, including our principal executive officer and principal financial officer, of the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(b) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). We have established disclosure controls and procedures designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms and is accumulated and communicated to management, including the principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure.

Based upon that evaluation, our principal executive officer and principal financial officer, with the assistance of other members of the Company's management, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) as of the end of the period covered by this annual report and has determined that our disclosure controls and procedures were not effective due to the material weaknesses as described herein.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of April 30, 2024. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control-Integrated 2013 Framework. Our management has concluded that, as of April 30, 2024, our internal control over financial reporting was not effective.

A material weakness is a control deficiency (within the meaning of the Public Company Accounting Oversight Board (United States) Auditing Standard No. 2) or combination of control deficiencies that result in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected. Management has identified the following material weaknesses:

1. We do not have sufficient resources in our accounting department, which restricts our ability to perform sufficient reviews and approval of manual journal entries posted to the general ledger and to consistently execute review procedures over general ledger account reconciliations, financial statement preparation and accounting for non-routine transactions; and

2. Our primary user access controls (i.e., provisioning, de-provisioning, privileged access and user access reviews) to ensure appropriate authorization and segregation of duties that would adequately restrict user and privileged access to the financially relevant systems and data to appropriate personnel were not designed and/or implemented effectively. We did not design and/or implement sufficient controls for program change management to certain financially relevant systems affecting our processes.

Planned Remediation

We are implementing measures designed to improve our internal control over financial reporting to remediate material weaknesses, including the following:

- Continue to formalize our internal control documentation and strengthening supervisory reviews by our management; and
- Developing plans to add additional qualified accounting personnel and segregate duties amongst accounting personnel.

Management continues to work to improve its controls related to our material weaknesses, specifically relating to user access and change management surrounding our information technology systems and applications. Management will continue to implement measures to remediate material weaknesses, such that these controls are designed, implemented, and operating effectively. The remediation actions include: (i) enhancing design and documentation related to both user access and change management processes and control activities; and (ii) developing and communicating additional policies and procedures to govern the area of information technology change management. In order to achieve the timely implementation of the above, management has commenced the following actions and will continue to assess additional opportunities for remediation on an ongoing basis:

- Engaging a third-party specialist to assist management with improving the Company's overall control environment, focusing on change management and access controls; and

- Implementing new applications and systems that are aligned with management's focus on creating strong internal controls.

We are currently working to improve and simplify our internal processes and implement enhanced controls, as discussed above, to address the material weaknesses in our internal control over financial reporting and to remedy the ineffectiveness of our disclosure controls and procedures. These material weaknesses will not be considered to be remediated until the applicable remediated controls are operating for a sufficient period of time and management has concluded, through testing, that these controls are operating effectively.

Despite the existence of these material weaknesses, we believe that the financial statements included in the period covered by this Annual Report on Form 10-K fairly present, in all material respects, our financial condition, results of operations and cash flows for the periods presented in conformity with U.S. generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

During the fourth fiscal quarter of 2024, there were no changes in our internal control over financial reporting which were identified in connection with management's evaluation required by paragraph (d) of Rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

Trading Plans

During the three months ended April 30, 2024, no director or Section 16 officer of the Company adopted or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the names and ages of our executive officers, directors and director nominees, and their positions with us, as of the date of this Annual Report:

Name	Age	Position
Stephan Jackman	48	Chief Executive Officer and Director
David J. Katzoff	62	Chief Financial Officer
Henry Nisser	55	Executive Vice President, General Counsel and Director
Kenneth S. Cragun	63	Senior Vice President of Finance
William B. Horne	56	Chairman of the Board
Milton C. Ault III	54	Vice Chairman of the Board
Mark Gustafson	64	Director
Lynne Fahey McGrath, M.P.H., Ph.D.	69	Director
Jeffrey Oram	57	Director
Andrew H. Woo, M.D., Ph.D.	61	Director

The following information provides a brief description of the business experience of each executive officer and director.

Stephan Jackman joined our company as Chief Executive Officer in November 2018. Mr. Jackman was elected as a director in September 2020. He has played an intricate role in the development of therapeutic treatments, products and programs from the research stage to market and commercialization. Mr. Jackman has demonstrated a dedicated dual focus of creating value for internal and external stakeholders while developing strategic alliances and cross-function teams to meet and exceed goals. Prior to joining our company, from October 2017 to November 2018, Mr. Jackman was the Chief Operating Officer of Ennaid Therapeutics, an emerging biopharmaceutical company focusing on cures for mosquito borne infectious diseases such as Zika and Dengue viruses. From October 2015 to October 2017, Mr. Jackman was Chief Operating Officer of Exit 9 Technologies, a technology startup with a digital platform that connects retailers, publishers and customers. Additionally, from August 2014 to October 2015, he was an independent project and management consultant assisting startups, Fortune 500 companies and non-profits with major strategic initiatives. He has also held positions of increasing responsibility at Novartis Pharmaceuticals Corporation, L'Oréal USA, SBM Management Services and Family Intervention Services. Mr. Jackman holds a Master of Science in Management and a Bachelor of Engineering in Mechanical Engineering from Stevens Institute of Technology.

David J. Katzoff joined our company on a part-time basis in November 2019, serving as our Senior Vice President of Operations from November 2019 to December 2020, as our Chief Operating Officer from December 2020 until August 2022 and currently serves as our Chief Financial Officer since August 2022. Mr. Katzoff has served as Senior Vice President of Finance of AULT since January 2019. Since February 2021, Mr. Katzoff has served as the Vice President of Finance of Ault Disruptive Technologies Corporation, a publicly traded special purpose acquisition company ("Ault Disruptive"). From December 2021 to September 2023, Mr. Katzoff served as the Chief Financial Officer of TurnOnGreen, Inc. (formerly, Imperalis Holding Corp.) ("TurnOnGreen"), an OTCQB quoted company. From 2015 to 2018, Mr. Katzoff served as Chief Financial Officer of Lumina Media, LLC, a privately-held media company and publisher of life-style publications. From 2003 to 2017, Mr. Katzoff served a Vice President of Finance of Local Corporation, a publicly-held local search company. Mr. Katzoff received a B.S. degree in Business Management from the University of California at Davis.

Henry C.W. Nisser has served as our Executive Vice President and General Counsel on a part-time basis since May 2019. Mr. Nisser was appointed as a director in September 2020. Since May 2019, Mr. Nisser has served as the Executive Vice President and General Counsel of AULT and as one of its directors since September 2020; he became AULT's President on January 12, 2021. Since March 2023, Mr. Nisser has served as the President, General Counsel and director of RiskOn International, Inc., an OTCPK quoted company ("ROI"). Since February 2021, Mr. Nisser has served as the President, General Counsel and a director of Ault Disruptive. Since April 2023, Mr. Nisser has served as a director of The Singing Machine Company, Inc., an issuer listed on Nasdaq ("MICS"). Mr. Nisser is the Executive Vice President and General Counsel of Avalanche International Corp., a publicly traded Nevada company categorized as a "voluntary filer" (not required to file periodic reports) ("Avalanche"). Mr. Nisser has served as a President, General Counsel and a director of Ault & Co. since May 2019. From October 2011 through April 2019, Mr. Nisser was an associate and

subsequently a partner with Sichenzia Ross Ference LLP, a law firm in New York. While with this law firm, his practice was concentrated on national and international corporate law, with a particular focus on U.S. securities compliance, public as well as private M&A, equity and debt financings and corporate governance. Mr. Nisser received his B.A. degree from Connecticut College, where he majored in International Relations and Economics. He received his LL.B. from University of Buckingham School of Law in the United Kingdom.

Kenneth S. Cragun joined our company on a part-time basis in December 2018. Since February 2021, Mr. Cragun has served as the Chief Financial Officer of Ault Disruptive. Since August 2020, Mr. Cragun has served as the Chief Financial Officer of AULT and between October 2018 and August 2020, served as its Chief Accounting Officer. Since September 2018, Mr. Cragun has served on the board of directors and Chairman of the Audit Committee of Verb Technology Company, Inc. Since July 2022, Mr. Cragun has served on the board of directors of MICS. He served as a CFO Partner at Hardesty, LLC, a national executive services firm between October 2016 and October 2018. His assignments at Hardesty included serving as Chief Financial Officer of CorVel Corporation, a publicly traded company and a nationwide leader in technology driven, healthcare-related, risk management programs, and of RISA Tech, Inc., a private structural design and optimization software company. Mr. Cragun was also Chief Financial Officer of two Nasdaq-traded companies, Local Corporation, from April 2009 to September 2016, which operated Local.com, a U.S. top 100 website, and Modtech Holdings, Inc., from June 2006 to March 2009, a supplier of modular buildings. Prior thereto, he had financial leadership roles with increasing responsibilities at MIVA, Inc., ImproveNet, Inc., NetCharge Inc., C-Cube Microsystems, Inc, and 3-Com Corporation. Mr. Cragun began his professional career at Deloitte. Mr. Cragun holds a Bachelor of Science degree in accounting from Colorado State University-Pueblo.

William B. Horne has served as a director of our company since June 2016 and upon the effectiveness of our initial public offering in June 2021, Mr. Horne become our Chairman of the Board. Mr. Horne served as our Chief Financial Officer from June 2016 through December 2018. Mr. Horne has been a member of the board of directors of AULT since October 2016. In January 2018, Mr. Horne was appointed as AULT's Chief Financial Officer until August 2020, when he resigned as its Chief Financial Officer and was appointed as its President. On January 12, 2021, Mr. Horne resigned as AULT's President and became its Chief Executive Officer. Mr. Horne has served as a director and Chief Executive Officer of Ault Disruptive since its inception in February 2021. Mr. Horne has served as a director and Chief Financial Officer of Avalanche since June 2016. Mr. Horne has served as a director and Chief Financial Officer of Ault & Co. since October 2017. He served as the Chief Financial Officer of Targeted Medical Pharma, Inc. from August 2013 to May 2019. Mr. Horne previously held the position of Chief Financial Officer in various public and private companies in the healthcare and high-tech field. Mr. Horne has a Bachelor of Arts Magna Cum Laude in Accounting from Seattle University.

Milton C. Ault, III has served as a director of our company since January 2024. Mr. Ault is the Company's founder and served as Chairman and a director from inception in 2016 until the Company's initial public offering in June 2021. Since January 2021, Mr. Ault has served as the Executive Chairman of AULT. Between December 2017 and January 2021, Mr. Ault was the Chief Executive Officer of AULT and between March 2017 and December 2017, Mr. Ault served as the Executive Chairman of AULT. Mr. Ault has served as the Chairman of the Board of Ault Disruptive since its incorporation in February 2021. Since January 2024, Mr. Ault has served as the Chairman and Chief Executive Officer of ROI. Since April 2023, Mr. Ault has served as the Executive Chairman of the board of directors of MICS. Mr. Ault has served as Chairman and Chief Executive Officer of Ault & Co. since December 2015, and as Chairman of Avalanche since September 2014. Since January 2011, Mr. Ault has been the Vice President of Business Development for MCKEA Holdings, LLC, a family office ("MCKEA"). Mr. Ault is a seasoned business professional and entrepreneur who has spent more than twenty-seven years identifying value in various financial markets including equities, fixed income, commodities, and real estate. Throughout his career, Mr. Ault has consulted for a few publicly traded and privately held companies, providing each of them the benefit of his diversified experience, that range from development stage to seasoned businesses.

Mark Gustafson joined our Board and became the Chairman of the Audit Committee in June 2021. Mr. Gustafson is a Chartered Professional Accountant with over 35 years of corporate, private and public company experience. Since June 2024, Mr. Gustafson has been the Chief Financial Officer of Orga Energy Ltd., a private oil and gas production company based in Calgary, Alberta. From January 2023 to June 2024, Mr. Gustafson was a director and non-executive Chairman of BrainLuxury, Inc., a private U.S. company that is developing and selling nutrients for the brain. Since April 2021, Mr. Gustafson has been the Chief Financial Officer, and since January 2022, a director, for PharmaKure Limited, a private London-based biopharmaceutical company dedicated to the treatment of neurodegenerative diseases. Between December 2021 and December 2023, Mr. Gustafson served as an independent director and Chairman of the Audit Committee of Ault Disruptive. From June 2020 to March 2024, Mr. Gustafson was a director of Alpha Helium Inc., a private Canadian-based company helium exploration company. From 2014 to 2020, he was the Chief Executive Officer of Challenger Acquisitions Limited, a London Stock Exchange listed entertainment company. From 2010 to 2012, Mr. Gustafson was the President and Chief Executive Officer of Euromax Resources Limited, a Toronto Stock Exchange listed mineral exploration company. From 2005 to 2009, he served as Chairman and Chief Executive Officer of Triangle Energy Corporation, a New York Stock Exchange listed oil and gas exploration company, from 2004 to 2006, he served as President and Chief Executive Officer of Torrent Energy Corporation, a private oil and gas company, and from 2001 to 2002, he served as a financial consultant for Samson Oil & Gas and Peavine Resources, two private oil and gas companies. From 1997 to 1999, Mr. Gustafson served as President and Chief Executive Officer of Total Energy Services Ltd., a Toronto Stock Exchange listed oilfield services company, from 1993 to 1995, he served as the Chief Financial Officer of Q/media Software Corporation, a Toronto Stock Exchange listed software company, and from 1987 to 1993, he served initially as the Chief Financial Officer and then as a Vice President in charge of two operating divisions at EnServ Corporation, a Toronto Stock Exchange listed oilfield services company. From 1981 to 1987, he served as an audit manager at Price Waterhouse in Calgary Alberta. Mr. Gustafson received his Bachelor of Business Administration from Wilfrid Laurier University. Mr. Gustafson has been a Chartered Accountant since 1983.

Lynne Fahey McGrath, M.P.H., Ph.D. joined our Board in June 2021. Dr. McGrath has served as a consultant to various companies in the biopharmaceutical industry, including: to the executive team of Nobias Therapeutics, Inc., a biotechnology product development company, between May 2020 and December 2021; a regulatory consultant with FoxKiser, LLC, a biotechnology consulting firm, from August 2018 to March 2020; and a regulatory consultant with Catalyst Healthcare Consulting, a biotechnology consulting firm, from 2020 to 2021. Dr. McGrath was a senior lead and Vice President of Regulatory Affairs at Regenxbio, Inc., where she headed global strategy for its portfolio of gene therapy products, from April 2015 to July 2018. Previously, she held senior positions at Novartis Corporation including Vice President, Global Head of Regulatory Affairs at Novartis Consumer Health and U.S. Head of Regulatory Affairs at Novartis Oncology from 2003 to April 2015. Dr. McGrath received a B.S. degree from the University of Connecticut, M.S. in Environmental Science from Rutgers University and M.P.H. and Ph.D. in Public Health from the University of Medicine and Dentistry of New Jersey Robert Wood Johnson Medical School.

Jeffrey Oram joined our Board in June 2021. Mr. Oram is a business professional with more than 25 years of corporate, private and institutional investment experience. Mr. Oram has spent the last 13 years in the institutional real estate capital markets. Since 2016, he has been a Principal at Godby Realtors, a private real estate investment and brokerage firm. From 2010 to 2018, Mr. Oram served as an Executive Member of the New Jersey State Investment Council, which oversees the investment of the State of New Jersey's pension fund. From 2011 to 2016, he served as Executive Managing Director at Colliers International, from 2009 to 2011 he served as Director at Marcus and Millichap, and from 2003 to 2009, served as First Vice President at CB Richard Ellis. Mr. Oram received a Bachelor of Science degree in Biology from Princeton University.

Andrew H. Woo, M.D., Ph.D. joined our Board in June 2021. Dr. Woo is in private practice at Santa Monica Neurological Consultants and serves as an Assistant Clinical Professor of Neurology at the David Geffen School of Medicine at UCLA and Cedars-Sinai Medical Center. He also serves on the

board for the Multiple Sclerosis Association of America and its Navigating MS International Steering Committee. He has been presented with UCLA clinical faculty teaching awards in 2006, 2012 and 2019 and is listed in America's Top Physicians by the Consumer Research Council of America and Castle Connolly America's Top Doctors 2006, 2007, 2010-2021, Southern California Super Doctors since 2008, and Los Angeles Magazine Top Doctors. He is an invited speaker at the Muntada International Symposium in Abu Dhabi. Dr. Woo received his B.A. from Cornell University and completed his M.D. and Ph.D. in Neuroimmunology in the Department of Molecular and Cell Biology at Brown University. He completed his medicine internship at Weil-Cornell Presbyterian Hospital/Cornell Medical Center in New York, his neurology residency at UCLA, and his fellowship in neurophysiology at Harbor-UCLA.

Board Leadership Structure and Risk Oversight

Our Board is currently chaired by Mr. Horne. Mr. Horne has been a director since June 2016 and served as our Chief Financial Officer from June 2016 until December 2018. Given Mr. Horne's extensive history with and knowledge of our company, we believe his role as our Chairman facilitates a regular flow of information between the Board and management and ensures that they both act with a common purpose.

One of the key functions of our Board is informed oversight of our risk management process. Our Board does not have a standing risk management committee, but rather administers this oversight function directly through the Board as a whole, as well as through various standing committees of our Board that address risks inherent in their respective areas of oversight. In particular, our Board is responsible for monitoring and assessing strategic risk exposure, including a determination of the nature and level of risk appropriate for us. Our Audit Committee has the responsibility to consider and discuss our major financial risk exposures and the steps our management has taken to monitor and control these exposures, including guidelines and policies to govern the process by which risk assessment and management is undertaken. The Audit Committee also monitors compliance with legal and regulatory requirements, in addition to oversight of the performance of our internal audit function. Our Nominating and Corporate Governance Committee monitors the effectiveness of our corporate governance guidelines, including whether they are successful in preventing illegal or improper liability-creating conduct. Our Compensation Committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our Board has an Audit Committee, a Compensation Committee and a Nominating and Corporate Governance Committee. The responsibilities of the Audit Committee (which consists of Mr. Gustafson (Chair), Mr. Oram and Dr. Woo) include recommending to the Board the independent registered public accounting firm to be retained by our company, reviewing with our independent registered public accounting firm the scope and results of their audits, and reviewing with the independent registered public accounting firm and management our accounting and reporting principles, policies and practices, as well as our accounting, financial and operating controls and staff. The Compensation Committee (which consist of Dr. McGrath (Chair), Mr. Gustafson and Mr. Oram) has responsibility for establishing and reviewing employee compensation. The Compensation Committee also has responsibility for administering and interpreting the Alzamend Neuro, Inc. 2021 Stock Incentive Plan, and determining the recipients, amounts and other terms (subject to the requirements of the Plan) of stock options and other equity-based awards which may be granted under the 2021 Stock Incentive Plan from time to time. The purpose of the Nominating and Corporate Governance Committee (which consist of Mr. Oram (Chair), Dr. McGrath and Dr. Woo) is to select, or recommend for our entire Board's selection, the individuals to stand for election as directors at the annual meeting of stockholders, as well as to consider the adequacy of our corporate governance and oversee and approve management continuity planning processes.

Certain Board Arrangements

In May 2021, the Board and Mr. Ault, our Founder and Chairman Emeritus, agreed to certain arrangements with regard to our Board composition and other matters. Contemporaneously with the consummation of the initial public offering, and in consideration for (i) the conversion of 750 shares of our series A convertible preferred stock beneficially owned by Mr. Ault through ALSI into 100,000 shares of common stock, (ii) the extension of the maturity date of the promissory note in the original principal amount of $15,000,000 (the "***ALSF Note***") issued to us by ALSF to December 31, 2023, and (iii) the resignation of Mr. Ault as a director and executive officer of our company, the Board agreed that William B. Horne be named our Chairman of the Board and remain in that position for so long as Mr. Ault beneficially owns no less than 5% of the outstanding shares of common stock (for which Mr. Horne will be paid $50,000 per year for his services), and Mr. Nisser remains a member of our Board for so long as Mr. Ault beneficially owns no less than 5% of the outstanding shares of common stock (for no additional remuneration). Additionally, Mr. Ault will hold the position of Founder and Chairman Emeritus and, as such, have the right to nominate an observer to our Board for a period of five years after the closing date of the initial public offering. Immediately following the closing of the initial public offering in June 2021, we entered into a five-year consulting agreement with Mr. Ault under which he will provide strategic advisory and consulting services to us in consideration for annual fees of $50,000. Upon Mr. Ault's reappointment to the Board in January 2024, the consulting agreement was terminated.

Term of Office

Directors serve until the next annual meeting of our stockholders and until their successors are elected and qualified. Officers are appointed to serve at the discretion of our Board.

Family Relationships

There are no family relationships among any of our executive officers and directors.

Involvement in Certain Legal Proceedings

Except as set forth below, to the best of our knowledge, during the past 10 years, none of the following occurred with respect to a present or former director, executive officer or employee:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time; *
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated; **

- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; and

- or been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.

* Mr. Cragun served as Chief Financial Officer of Local Corporation (April 2009 to September 2016), formerly based in Irvine, California, and, in June 2015, Local Corporation filed a voluntary petition in the United States Bankruptcy Court for the Central District of California seeking relief under the provisions of Chapter 11 of Title 11 of the United States Code.

** Please see the press release issued by AULT on August 15, 2023.

Except as disclosed in “Certain Relationships and Related Party Transactions,” none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the SEC.

Code of Business Conduct and Ethics

Our Board has adopted a written code of business conduct and ethics, revised effective May 25, 2021, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions (the “Code of Conduct and Ethics”). In addition, on May 25, 2021, we adopted Code of Ethics for our Chief Executive Officer and our Senior Financial Officers (the “Code of Ethics”). We have posted on our website a current copy of both codes and all disclosures that are required by law in regard to any amendments to, or waivers from, any provision of the Code of Conduct and Ethics.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth summary compensation information for the following persons: (i) all persons serving as our principal executive officer during the years ended April 30, 2024 and 2023, and (ii) up to our two other most highly compensated executive officers who received compensation during the years ended April 30, 2024 and 2023, who were executive officers on the last day of our fiscal year. We refer to these persons as our “named executive officers” in this Annual Report. The following table includes all compensation earned by the named executive officers for the respective period, regardless of whether such amounts were actually paid during the period:

Name and principal position	Year	Salary ($)	Bonus ($)	Stock award ($)	Option Awards[(1)] ($)	All Other Compensation[(2)] ($)	Total ($)
Stephan S. Jackman	2024	350,000	75,000	—	—	18,617	443,617
Chief Executive Officer	2023	300,000	120,000	—	1,789,375	14,236	2,223,611
David J. Katzoff (3)	2024	150,000	—	—	—	—	150,000
Chief Financial Officer	2023	116,667	—	—	—	—	116,667

(1) The values reported in the “Option Awards” column represents the aggregate grant date fair value, computed in accordance with ASC 718, *Share Based Payments*, of grants of stock options to each of our named executive officers and directors.
(2) The amounts included in “All Other Compensation” consist of health insurance benefits.
(3) Mr. Katzoff was appointed our Chief Financial Officer on August 5, 2022. Prior thereto that he was our Chief Operating Officer.

Employment Agreements

None.

CEO Pay Ratio

As required by Section 953(b) of the Dodd-Frank Wall Street Reform and Consumer Protection Act, we are providing disclosure regarding the ratio of annual total compensation of Mr. Jackman, our Chief Executive Officer, to that of our median employee. Our median employee earned $130,000 in total compensation for our fiscal year ended April 30, 2024. Based upon the total fiscal year 2024 compensation reported for Mr. Jackman of $443,617 as reported under “Total” in the Summary Compensation Table, our ratio of PEO to median employee pay was 3:1.

Calculation Methodology

To identify our median employee, we identified our total employee population worldwide as of April 30, 2024, excluding our Chief Executive Officer, in accordance with SEC rules. On April 30, 2024, all of our employee population was located in the U.S.

We collected full-year fiscal year 2024 actual gross earnings data for the April 30, 2024 employee population, including cash-based compensation and equity-based compensation that was realized in fiscal year 2024, relying on our internal payroll records. Compensation was annualized on a straight-line basis for non-temporary new hire employees who did not work with our company for the full calendar year.

Once we determined the median employee, we calculated total compensation for the median employee in the same manner in which we determine the compensation shown for our named executive officers in the Summary Compensation Table, in accordance with SEC rules.

Policies on Ownership, Insider Trading, 10b5-1 Plans and Hedging

We do not have formal stock ownership guidelines for our employees or directors, because the Board is satisfied that stock and option holdings among our employees or directors are sufficient at this time to provide motivation and to align this group's interests with those of our stockholders.

We have established an insider trading policy that provides guidelines to, and imposes restrictions on, officers, directors and employees with respect to transactions in our securities. Our insider trading policy prohibits certain actions by such individuals relating to buying and selling our common stock, and discourages certain other actions in other situations. Such individuals are authorized to enter into trading plans established according to Section 10b5-1 of the Exchange Act with an independent broker-dealer. Under these plans, the individual must not exercise any influence over the amount of the securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party. Such plans provide a defense from insider trading liability.

We have not adopted any hedging policies.

Outstanding Equity Awards at Fiscal Year End

The following table provides information on outstanding equity awards as of April 30, 2024 awarded to our named executive officers:

	OUTSTANDING EQUITY AWARDS AT APRIL 30, 2024				
	Option Awards				
Name	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Stephan Jackman	20,000	-	-	150.00	11/15/2028
	-	13,333	13,333	225.00	11/18/2029
	-	13,333	13,333	175.50	11/29/2032
David J. Katzoff	2,666	-	-	150.00	1/21/2029
	4,840	826	-	225.00	11/1/2029
	1,424	243	-	225.00	11/26/2029
	-	6,666	6,666	225.00	11/18/2029

Incentive Compensation Plans

2016 Stock Incentive Plan

In April 2016, our stockholders approved our company's 2016 Stock Incentive Plan (the "2016 Plan"). The 2016 Plan provides for the issuance of a maximum of 83,333 shares of our common stock to be offered to our directors, officers, employees and consultants. On March 1, 2019, our stockholders approved an additional 50,000 shares to be available for issuance under the 2016 Plan. Options granted under the 2016 Plan have an exercise price equal to or greater than the fair value of the underlying common stock at the date of grant and become exercisable based on a vesting schedule determined at the date of grant. The options expire between five and 10 years from the date of grant. Restricted stock awards granted under the 2016 Plan are subject to a vesting period determined at the date of grant.

2021 Stock Incentive Plan

In February 2021, our Board adopted, and our stockholders approved, the Alzamend Neuro, Inc. 2021 Stock Incentive Plan (the "2021 Plan"). The 2021 Plan authorizes the grant to eligible individuals of (1) stock options (incentive and non-statutory), (2) restricted stock, (3) stock appreciation rights, or SARs, (4) restricted stock units, and (5) other stock-based compensation.

Stock Subject to the 2021 Plan. The maximum number of shares of our common stock that may be issued under the 2021 Plan is 66,666 shares, which number will be increased to the extent that compensation granted under the 2021 Plan is forfeited, expires or is settled for cash (except as otherwise provided in the 2021 Plan). Substitute awards (awards made or shares issued by us in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company that we acquire or any subsidiary of ours or with which we or any subsidiary combines) will not reduce the shares authorized for grant under the 2021 Plan, nor will shares subject to a substitute award be added to the shares available for issuance or transfer under the 2021 Plan.

No Liberal Share Recycling. Notwithstanding anything to the contrary, any and all stock that is (i) withheld or tendered in payment of an option exercise price; (ii) withheld by us or tendered by the grantee to satisfy any tax withholding obligation with respect to any award; (iii) covered by a SAR that it is settled in stock, without regard to the number of shares of stock that are actually issued to the grantee upon exercise; or (iv) reacquired by us on the open market or otherwise using cash proceeds from the exercise of options, will not be added to the maximum number of shares of stock that may be issued under the 2021 Plan.

Eligibility. Employees of, and consultants to, our company or our affiliates and members of our Board are eligible to receive equity awards under the 2021 Plan. Only our employees, and employees of our parent and subsidiary corporations, if any, are eligible to receive incentive stock options. Employees, directors (including non-employee directors) and consultants of or for our company and our affiliates are eligible to receive non-statutory stock options, restricted stock, purchase rights and any other form of award the 2021 Plan authorizes.

Purpose. The purpose of the 2021 Plan is to promote the interests of our company and our stockholders by providing executive officers, employees, non-employee directors, and key advisors of our company and our subsidiaries with appropriate incentives and rewards to encourage them to enter into and remain in their positions with us and to acquire a proprietary interest in our long-term success, as well as to reward the performance of these individuals in fulfilling their personal responsibilities for long-range and annual achievements.

Administration. Unless otherwise determined by the Board, the Compensation Committee administers the 2021 Plan. The Compensation Committee is composed solely of "non-employee directors" within the meaning of Rule 16b-3 under the Exchange Act, "outside directors" within the meaning of Section 162(m) of the Internal Revenue Code, and "independent directors" within the meaning of the Nasdaq Marketplace Rules. The Compensation Committee has the power, in its discretion, to grant awards under the 2021 Plan, to select the individuals to whom awards are granted, to

determine the terms of the grants, to interpret the provisions of the 2021 Plan and to otherwise administer the 2021 Plan. Except as prohibited by applicable law or any rule promulgated by a national securities exchange to which our company may in the future be subject, the Compensation Committee may delegate all or any of its responsibilities and powers under the 2021 Plan to one or more of its members, including, without limitation, the power to designate participants and determine the amount, timing and term of awards under the 2021 Plan. In no event, however, will the Compensation Committee have the power to accelerate the payment or vesting of any award, other than in the event of death, disability, retirement or a change of control of our company.

The 2021 Plan provides that members of the Compensation Committee will be indemnified and held harmless by us from any loss or expense resulting from claims and litigation arising from actions related to the 2021 Plan.

Term. The 2021 Plan was effective as of February 17, 2021, and awards may be granted through February 16, 2031. No awards may be granted under the 2021 Plan subsequent to that date. The Board may suspend or terminate the 2021 Plan without stockholder approval or ratification at any time or from time to time.

Amendments. Subject to the terms of the 2021 Plan, the Compensation Committee, as administrator, has the sole discretion to interpret the provisions of the 2021 Plan and outstanding awards. Our Board generally may amend or terminate the 2021 Plan at any time and for any reason, except that no amendment, suspension or termination may impair the rights of any participant without his or her consent, and except that approval of our stockholders is required for any amendment which, among provisions, increases the number of shares of common stock subject to the 2021 Plan, decreases the price at which grants may be granted and reprices existing options.

Repricing Prohibition. Other than in connection with certain corporate events, the Compensation Committee will not, without the approval of our stockholders, (a) lower the option price per share of an option or SAR after it is granted, (b) cancel an option or SAR when the exercise price per share exceeds the fair market value of one share in exchange for cash or another award (other than in connection with a change of control), or (c) take any other action with respect to an option or SAR that would be treated as a repricing under the rules and regulations of the principal U.S. national securities exchange on which our shares are then listed.

Minimum Vesting Requirement. Grantees of full-value awards (i.e., awards other than options and SARs), will be required to continue to provide services to us or an affiliated company) for not less than one-year following the date of grant in order for any such full-value awards to fully or partially vest (other than in case of death, disability or a Change of Control). Notwithstanding the foregoing, up to 5% of the available shares of stock authorized for issuance under the 2021 Plan may provide for vesting of full-value awards, partially or in full, in less than one year.

Adjustments upon Changes in Capitalization. In the event of any merger, reorganization, consolidation, recapitalization, dividend or distribution (whether in cash, shares or other property, other than a regular cash dividend), stock split, reverse stock split, spin-off or similar transaction or other change in our corporate structure affecting our common stock or the value thereof, appropriate adjustments to the 2021 Plan and awards will be made as the Board determines to be equitable or appropriate, including adjustments in the number and class of shares of stock available for issuance under the 2021 Plan, the number, class and exercise or grant price of shares subject to awards outstanding under the 2021 Plan, and the limits on the number of awards that any person may receive.

Change of Control. Agreements evidencing awards under the 2021 Plan may provide that upon a Change of Control (as defined in the 2021 Plan), unless otherwise provided in the agreement evidencing an award), outstanding awards may be cancelled and terminated without payment if the consideration payable with respect to one share of stock in connection with the Change of Control is less than the exercise price or grant price applicable to such award, as applicable.

Notwithstanding any other provisions of the 2021 Plan to the contrary, the vesting, payment, purchase or distribution of an award may not be accelerated by reason of a Change of Control for any participant unless the Grantee's employment is involuntarily terminated as a result of the Change of Control as provided in the Award agreement or in any other written agreement, including an employment agreement, between us and the participant. If the Change of Control results in the involuntary termination of participant's employment, outstanding awards will immediately vest, become fully exercisable and may thereafter be exercised.

Generally, under the 2021 Plan, a Change of Control occurs upon (i) the consummation of a reorganization, merger or consolidation of our company with or into another entity, pursuant to which our stockholders immediately prior to the transaction do not own more than 50% of the total combined voting power after the transaction, (ii) the consummation of the sale, transfer or other disposition of all or substantially all of our assets, (iii) certain changes in the majority of our Board from those in office on the effective date of the 2021 Plan, (iv) the acquisition of more than 50% of the total combined voting power in our outstanding securities by any person, or (v) we are dissolved or liquidated.

Types of Awards

Stock Options. Incentive stock options and non-statutory stock options are granted pursuant to award agreements adopted by our Compensation Committee. Our Compensation Committee determines the exercise price for a stock option, within the terms and conditions of the 2021 Plan; provided, that the exercise price of an incentive stock option cannot be less than 100% of the fair market value of our common stock on the date of grant. Options granted under the 2021 Plan vest at the rate specified by our Compensation Committee.

The Compensation Committee determines the term of stock options granted under the 2021 Plan, up to a maximum of 10 years, except in the case of certain Incentive Stock Options, as described below. The Compensation Committee will also determine the length of period during which an optionee may exercise their options if an optionee's relationship with us, or any of our affiliates, ceases for any reason; for incentive stock options, this period is limited by applicable law. The Compensation Committee may extend the exercise period in the event that exercise of the option following termination of service is prohibited by applicable securities laws. In no event, however, may an option be exercised beyond the expiration of its term unless the term is extended in accordance with applicable law.

Acceptable consideration for the purchase of common stock issued upon the exercise of a stock option will be determined by the Compensation Committee and may include (a) cash or its equivalent, (b) delivering a properly executed notice of exercise of the option to us and a broker, with irrevocable instructions to the broker promptly to deliver to us the amount necessary to pay the exercise price of the option, (c) any other form of legal consideration that may be acceptable to the Compensation Committee or (d) any combination of (a), (b) or (c).

Unless the Compensation Committee provides otherwise, options are generally transferable in accordance with applicable law, provided that any transferee of such options agrees to become bound by the terms of the 2021 Plan. An optionee may also designate a beneficiary who may exercise the option following the optionee's death.

Incentive or Non-statutory Stock Options. Incentive stock options may be granted only to our employees, and the employees of our parent or subsidiary corporations, if any. The Compensation Committee may grant awards of incentive or non-statutory stock options that are fully vested on the date made, to any of our employees, directors or consultants. Option awards are granted pursuant to award agreements adopted by our Compensation Committee. To the extent required by applicable law, the aggregate fair market value, determined at the time of grant, of shares of our common stock with

respect to incentive stock options that are exercisable for the first time by an optionee during any calendar year may not exceed $100,000. To the extent required by applicable law, no incentive stock option may be granted to any person who, at the time of the grant, owns or is deemed to own stock possessing more than 10% of our total combined voting power or that of any of our affiliates unless (a) the option exercise price is at least 110% of the fair market value of the stock subject to the option on the date of grant and (b) the term of the incentive stock option does not exceed five years from the date of grant.

Stock Appreciation Rights. An SAR is the right to receive stock, cash, or other property equal in value to the difference between the grant price of the SAR and the market price of our common stock on the exercise date. SARs may be granted independently or in tandem with an option at the time of grant of the related option. An SAR granted in tandem with an option will be exercisable only to the extent the underlying option is exercisable. An SAR confers on the grantee a right to receive an amount with respect to each share of common stock subject thereto, upon exercise thereof, equal to the excess of (A) the fair market value of one share of common stock on the date of exercise over (B) the grant price of the SAR (which in the case of an SAR granted in tandem with an option will be equal to the exercise price of the underlying option, and which in the case of any other SAR will be such price as the Compensation Committee may determine but in no event will be less than the fair market value of a share of common stock on the date of grant of such SAR).

Restricted Stock and Restricted Stock Units. Restricted stock is common stock that we grant subject to transfer restrictions and vesting criteria. A restricted stock unit is a right to receive stock or cash equal to the value of a share of stock at the end of a specified period that we grant subject to transfer restrictions and vesting criteria. The grant of these awards under the 2021 Plan are subject to such terms, conditions and restrictions as the Compensation Committee determines consistent with the terms of the 2021 Plan.

At the time of grant, the Compensation Committee may place restrictions on restricted stock and restricted stock units that will lapse, in whole or in part, only upon the attainment of performance goals; provided that such performance goals will relate to periods of performance of at least one fiscal year, and if the award is granted to a 162(m) officer, the grant of the award and the establishment of the performance goals will be made during the period required under Internal Revenue Code Section 162(m). Except to the extent restricted under the award agreement relating to the restricted stock, a grantee granted restricted stock will have all of the rights of a stockholder, including the right to vote restricted stock and the right to receive dividends.

Unless otherwise provided in an award agreement, upon the vesting of a restricted stock unit, there will be delivered to the grantee, within 30 days of the date on which such award (or any portion thereof) vests, the number of shares of common stock equal to the number of restricted stock units becoming so vested.

Other Stock-Based Awards. The 2021 Plan also allows the Compensation Committee to grant “Other Stock-Based Awards,” which means a right or other interest that may be denominated or payable in, valued in whole or in part by reference to, or otherwise based on, or related to, common stock. Subject to the limitations contained in the 2021 Plan, this includes, without limitation, (i) unrestricted stock awarded as a bonus or upon the attainment of performance goals or otherwise as permitted under the 2021 Plan, and (ii) a right to acquire stock from us containing terms and conditions prescribed by the Compensation Committee. At the time of the grant of other stock-based awards, the Compensation Committee may place restrictions on the payout or vesting of other stock-based awards that will lapse, in whole or in part, only upon the attainment of performance goals; provided that such Performance Goals will relate to periods of performance of at least one fiscal year, and if the award is granted to a 162(m) Officer, the grant of the Award and the establishment of the performance goals will be made during the period required under Internal Revenue Code Section 162(m). Other Stock-Based Awards may not be granted with the right to receive dividend equivalent payments.

Performance Awards. Performance awards provide participants with the opportunity to receive shares of our common stock, cash or other property based on performance and other vesting conditions. Performance awards may be granted from time to time as determined at the discretion of the Board, or the Compensation Committee (as applicable). Subject to the share limit and maximum dollar value set forth above under “*Limits per Participant*,” the Board, or the Compensation Committee (as applicable), has the discretion to determine (i) the number of shares of common stock under, or the dollar value of, a performance award and (ii) the conditions that must be satisfied for grant or for vesting, which typically will be based principally or solely on achievement of performance goals.

Performance Criteria. With respect to awards intended to qualify as performance-based compensation under Code Section 162(m), a committee of “outside directors” (as defined in Code Section 162(m)) with authority delegated by our Board will determine the terms and conditions of such awards, including the performance criteria. The performance goals for restricted stock awards, restricted stock units, performance awards or other stock-based awards will be based on the attainment of specified levels of, among other metrics, the attainment of certain target levels of, or a specified percentage increase in, revenues, earnings, income before taxes and extraordinary items, net income, operating income, earnings before or after deduction for all or any portion of income tax, earnings before interest, taxes, depreciation and amortization or a combination of any or all of the foregoing.

The performance goals may be based solely by reference to our performance or the performance of one or more of our subsidiaries, parents, divisions, business segments or business units, or based upon the relative performance of other companies or upon comparisons of any of the indicators of performance relative to other companies. The authorized committee of outside directors may also exclude under the terms of the performance awards, the impact of an event or occurrence that the committee determines should appropriately be excluded, including restructurings, discontinued operations, extraordinary items, and other unusual or non-recurring charges, or changes in generally accepted accounting principles or practices.

Director Compensation

The Company pays each independent director an annual base amount of $25,000. Additionally, our Board makes recommendations for adjustments to an independent director’s compensation when the level of services provided are significantly above what was anticipated.

The table below sets forth, for each non-employee director, the total amount of compensation related to his or her service during the year ended April 30, 2024:

Name	Fees earned or paid in cash ($)	Stock awards ($)	Options awards ($)	All other compensation ($)	Total ($)
William B. Horne	50,000	-	-	-	50,000
Milton C. Ault III	8,333	-	-	-	8,333
Mark Gustafson	25,000	-	-	-	25,000
Lynne Fahey McGrath	25,000	-	-	-	25,000
Andy H. Woo	25,000	-	-	-	25,000
Jeffrey Oram	25,000	-	-	-	25,000

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table shows the beneficial ownership of our common stock as of July 29, 2024, held by (i) each person known by us to be the beneficial owner of more than 5% of our outstanding common stock, (ii) each of our directors and director nominees, (iii) each of our executive officers, and (iv) all of our directors, director nominees and executive officers as a group. As of July 29, 2024, there were 841,240 shares of our common stock issued and outstanding.

Beneficial ownership is determined in accordance with the rules of the SEC, and generally includes voting power and/or investment power with respect to the securities held. Shares of our common stock subject to options and warrants currently exercisable or which may become exercisable within 60 days of the date of this Annual Report, are deemed outstanding and beneficially owned by the person holding such options or warrants for purposes of computing the number of shares and percentage beneficially owned by such person but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person. Except as indicated in the footnotes to this table, the persons or entities named have sole voting and investment power with respect to all shares of our common stock shown as beneficially owned by them.

Unless otherwise noted in the footnotes to the following table, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to their beneficially owned common stock.

Unless otherwise indicated, the principal address of each of the persons below is c/o Alzamend Neuro, Inc., 3480 Peachtree Road NE, Second Floor, Suite 103, Atlanta, GA 30326.

Greater than 5% Beneficial Owners:	Number of shares of Common Stock Beneficially Owned	Percentage of Shares Beneficially Owned
Ault Life Sciences, Inc. (1)	99,619	11.84%
Ault Lending, LLC (2)	780,922	50.55%
Ault Alliance, Inc. (3)	781,033	50.55%
Directors and Executive Officers		
Milton C. Ault, III (1) (2) (3) (4)	897,887	58.11%
Stephan Jackman (5)	20,303	2.36%
David J. Katzoff (6)	10,599	1.24%
Henry C.W. Nisser (7)	8,333	*
Kenneth S. Cragun (8)	10,000	1.17%
William B. Horne (9)	18,333	2.15%
Mark Gustafson (10)	2,400	*
Lynne Fahey McGrath, M.P.H., Ph.D. (11)	2,500	*
Jeffrey Oram (12)	2,666	*
Andrew H. Woo, M.D., Ph.D. (12)	2,666	*
All directors and named executive officers as a group (10 persons)	975,688	60.45%

* Less than 1% of outstanding shares.

(1) Milton C. (Todd) Ault, III, our Founder and Vice Chairman, has sole voting and investment power with respect to the shares held of record by ALSI.

(2) Mr. Ault has voting and investment power with respect to the securities held by Ault Lending. Consists of (i) 77,169 shares of common stock and (ii) 703,753 shares of common stock issuable upon conversion of Series B Preferred Stock. Excludes (A) 210,000 shares of common stock underlying warrants that are not currently exercisable and (B) 22,222 shares of common stock underlying currently exercisable warrants due to a beneficial ownership blocker limitation provision contained therein. Notwithstanding the foregoing, Ault Lending is only permitted to cast a vote representing 240,549 shares of common stock, instead of the 703,753 shares of common stock issuable upon conversion of the Series B Preferred Stock, in accordance with the terms of the Amended and Restated Certificate of Designation of the Rights and Preferences of the Series B Preferred Stock.

(3) Mr. Ault has voting and investment power with respect to the securities held by AULT. Ault Lending is a wholly owned subsidiary of AULT. Consists of (i) 111 shares of common stock underlying currently exercisable warrants, (ii) 99,619 shares of common stock held by ALSI and (iii) 703,753 shares of common stock issuable upon conversion of Series B Preferred Stock held by Ault Lending. Excludes (A) 210,000 shares of common stock underlying warrants held by Ault Lending that are not currently exercisable and (B) 22,222 shares of common stock underlying currently exercisable warrants held by Ault Lending due to a beneficial ownership blocker limitation provision contained therein.

(4) Consists of (i) 16,686 shares of our common stock held by Mr. Ault, (ii) 77,169 shares of common stock held by Ault Lending, (iii) 703,753 shares of common stock issuable upon conversion of Series B Preferred Stock held by Ault Lending, (iv) 99,619 shares of common stock held by ALSI, (v) 549 shares of common stock held by Ault Life Sciences Fund, LLC (“ALSF”) and (vi) 111 shares of common stock underlying currently exercisable warrants held by Ault Alliance. Excludes (A) 210,000 shares of common stock underlying warrants held by Ault Lending that are not currently exercisable and (B) 22,222 shares of common stock underlying currently exercisable warrants held by Ault Lending due to a beneficial ownership blocker limitation provision contained therein. Mr. Ault has sole voting and investment power with respect to the securities held of record by ALSF.

(5) Consist of (i) 303 shares of our common stock and (ii) 20,000 shares of our common stock issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(6) Consists of (i) 540 shares of our common stock, (ii) 60 shares of our common stock issuable upon the exercise of warrants and (iii) 9,999 shares of our common stock issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(7) Represents shares of our common stock issuable upon the exercise of stock options, which are currently exercisable or exercisable within 60 days. Mr. Nisser’s address is 122 East 42nd Street, 50th Floor, Suite 5000, New York, New York 10168.

(8) Represents shares of our common stock issuable upon the exercise of stock options, which are currently exercisable or exercisable within 60 days.

(9) Consists of (i) 6,666 shares of our common stock and (ii) 11,666 shares of our common stock issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(10) Consists of (i) 400 shares of our common stock and (ii) 2,000 shares of our common stock issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

(11) Consists of (i) 500 shares of our common stock owned by Dr. McGrath and (ii) 2,000 shares of our common stock issuable upon the exercise of stock options owned by Dr. McGrath that are currently exercisable or exercisable within 60 days.

(12) Consists of (i) 666 shares of our common stock and (ii) 2,000 shares of our common stock issuable upon the exercise of stock options that are currently exercisable or exercisable within 60 days.

Equity Compensation Information

The following table summarizes information about our equity compensation plans as of April 30, 2024:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by stockholders	98,000	189.60	62,000
Equity compensation plans not approved by stockholders	32,333	230.60	-
Total	130,333	199.60	62,000

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS AND DIRECTOR INDEPENDENCE

Certain Relationships

Milton C. (Todd) Ault, III, our Founder and Vice Chairman, has significant influence over our Company, directly and through his controlling interests in AULT, Ault Lending and ALSI. Mr. Ault is also the Chairman, Chief Executive Officer and single largest beneficial stockholder (through Ault & Co.) of AULT. The Board and executive officers of our company and the board of directors and executive officers of AULT contain some of the same individuals. William B. Horne, the Chairman of the Board of our company, is the Chief Executive Officer and a director of AULT, Henry Nisser, our Executive Vice President, General Counsel and a director of our company, is the President, General Counsel and a director of AULT, and Kenneth S. Cragun, our Senior Vice President of Finance is the Chief Financial Officer of AULT.

Transactions with Related Persons

To the best of our knowledge, during our most recent fiscal year end on April 30, 2024, other than as set forth below, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds $32,736, or 1% of the average total assets at year-end for the last two completed fiscal years, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially more than 5% of any class of our common stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

On April 30, 2019, we entered into a securities purchase agreement with ALSF for the sale of 66,666 shares of common stock, plus 33,333 warrants with a five-year term and an exercise price of $450.00 per share and vesting upon issuance (the “ALSF Warrants”). The total purchase price of $15,000,000 was in the form of the ALSF Note. The ALSF Note balance as of April 30, 2020 was reduced by $16,800 reflecting payments made during the year ended April 30, 2020. The ALSF Note balance as of April 30, 2021 was reduced by $99,905 reflecting payments made during the year ended April 30, 2021. As of April 30, 2023, the ALSF Note balance was $14,883,295. The ALSF Note was due December 31, 2023. The control person of ALSF is Mr. Ault. ALSF is wholly owned by ALSI. ALSI is almost entirely wholly owned by Ault & Co., of which MCKEA, of which Mr. Ault’s spouse is the managing member, is the majority owner. As such, MCKEA is indirectly the majority owner of ALSF. The ALSF Note was secured by a stock pledge agreement dated June 11, 2019 (the “Pledge Agreement”).

On January 19, 2024, we entered into a settlement agreement with ALSF, pursuant to which ALSF returned 66,117 shares and the ALSF Warrants to us, in full settlement of the ALSF Note and the Pledge Agreement, as well as disputes and claims between the parties.

In May 2021, the Board and Mr. Ault, agreed to certain arrangements with regard to our Board composition and other matters. Contemporaneously with the consummation of the initial public offering, and in consideration for (i) the conversion of 750 shares of our series A convertible preferred stock beneficially owned by Mr. Ault through ALSI into 100,000 shares of common stock, (ii) the extension of the maturity date of the ALSF Note to December 31, 2023, and (iii) the resignation of Mr. Ault as a director and executive officer of our company, the Board agreed that William B. Horne be named our Chairman of the Board and remain in that position for so long as Mr. Ault beneficially owns no less than 5% of the outstanding shares of common stock (for which Mr. Horne will be paid $50,000 per year for his services), and Mr. Nisser remains a member of our Board for so long as Mr. Ault beneficially owns no less than 5% of the outstanding shares of common stock (for no additional remuneration). Additionally, Mr. Ault will hold the position of Founder and Chairman Emeritus and, as such, have the right to nominate an observer to our Board for a period of five years after the closing date of the initial public offering. Immediately following the closing of the initial public offering in June 2021, we entered into a five-year consulting agreement with Mr. Ault under which he will provide strategic advisory and consulting services to us in consideration for annual fees of $50,000. Upon Mr. Ault’s reappointment to the Board in January 2024, the consulting agreement was terminated.

In November 2022, we entered into a marketing and brand development agreement with AULT, effective August 1, 2022, whereby AULT provided various marketing services over twelve months valued at $1.4 million. We had the right to pay the fee in cash or shares of common stock with a value of $225.00 per share. On November 11, 2022, we elected to pay the fee with 6,222 shares of common stock.

On the January 31, 2024, we entered into the SPA with Ault Lending, pursuant to which we agreed to sell to Ault Lending up to 6,000 shares of Series B Preferred Stock and Series B Warrants to purchase up to 600,000 shares of common stock in one or more closings. On the Execution Date, we sold 1,220 shares of Series B Preferred Stock and Series B Warrants to purchase 122,000 shares of common stock to Ault Lending, for a total purchase price of $1.22 million, which was paid by the cancellation of $1.22 million of cash advances made by Ault Lending to us between November 9, 2023 and the Execution Date. Each share of Series B Preferred Stock is convertible into such number of Conversion Shares determined by dividing the Stated Value by the Conversion Price. The Series B Preferred Stock votes with the common stock, on an "as-converted" basis, subject to certain limitations as set forth in the Series B Certificate of Designations. The Series B Warrants grant Ault Lending the right to purchase Warrant Shares at the Exercise Price of $12.00 for a period of five years from the Initial Exercise Date.

On March 26, 2024, we sold 780 shares of Series B Convertible Preferred Stock and Series B Warrants to purchase 78,000 shares of common stock with an exercise price of $12.00, for a total purchase price of $780,000. On April 29, 2024, we sold 100 shares of Series B Convertible Preferred Stock and Series B Warrants to purchase 10,000 shares of common stock with an exercise price of $12.00, for a total purchase price of $100,000.

Our accounting and finance department use shared office space within the Costa Mesa offices of AULT.

Future Transactions

Our Board has adopted a policy whereby any future transactions between our company and any of our subsidiaries, affiliates, officers, directors, principal stockholders or any affiliates of the foregoing will be on terms no less favorable to us than could reasonably be obtained in "arm's length" transactions with independent third parties, and any such transactions will also be approved by a majority of our disinterested and independent outside directors.

Director Independence

Director	Independent	Audit Committee	Nominating and Governance Committee	Compensation Committee
Stephan Jackman	No			
William B. Horne	Yes			
Milton C. Ault	No			
Henry Nisser	No			
Mark Gustafson	Yes	C		X
Lynne Fahey McGrath	Yes		X	C
Jeffrey Oram	Yes	X	C	X
Andrew H. Woo	Yes	X	X	

C – Chairman of committee
X – Member of committee

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Baker Tilly US, LLP ("Baker Tilly") served as our independent registered public accounting firm for the year ended April 30, 2023. On May 6, 2024, our audit committee dismissed Baker Tilly and appointed Haskell & White LLP as our independent registered public accounting firm for the year ended April 30, 2024.

Fees and Services

The following table shows the aggregate fees paid to us for professional services by Baker Tilly for the years ended April 30, 2024 and 2023:

	2024	2023
Audit Services	$ 263,160	$ 140,779
Audit Related Services	48,600	—
Tax Services	—	6,811
All Other Services	—	—
Total	$ 311,760	$ 147,590

Audit Fee. This category includes the aggregate fees paid for professional services rendered for the audits of our financial statements during the years ended April 30, 2024 and 2023, for the reviews of the interim financial statements during the years ended April 30, 2024 and 2023, and for other services that are normally provided by the independent auditors in connection with statutory and regulatory filings or engagements for the relevant years. We have not paid Haskell & White LLP for any audit services as they were not engaged prior to April 30, 2024.

Audit-Related Fees. This category includes the aggregate fees paid in each of the last two years for assurance and related services by the independent auditors that are reasonably related to the performance of the audits or reviews of the financial statements and are not reported above under "Audit Fees," and generally consist of fees for other engagements under professional auditing standards, accounting and reporting consultations, internal control-related matters, and audits of employee benefit plans.

Tax Fees. This category includes the aggregate fees paid in each of the last two years for professional services rendered by the independent auditors for tax compliance, tax planning and tax advice.

All Other Fees. This category includes the aggregate fees paid in each of the last two years for products and services provided by the independent auditors that are not reported above under "Audit Fees," "Audit-Related Fees," or "Tax Fees."

The Audit Committee's policy is to pre-approve all services provided by our independent registered public accounting firm. These services may include audit services, audit-related services, tax services and other services. The Audit Committee may also pre-approve particular services on a case-by-case basis. Our independent auditors are required to report periodically to the Audit Committee regarding the extent of services they provide in accordance with such pre-approval.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Exhibit Description
3.1	Certificate of Incorporation (incorporated by reference to Exhibit 2.1 of Form DOS filed with the SEC on August 19, 2016).
3.2	Certificate of Amendment to the Certificate of Incorporation, filed with the Delaware Secretary of State on June 10, 2016 (incorporated by reference to Exhibit 3.2 of the Quarterly Report on Form 10-Q filed with the SEC on December 15, 2023).
3.3	Certificate of Amendment to the Certificate of Incorporation, filed with the Delaware Secretary of State on December 22, 2020 (incorporated by reference to Exhibit 3.3 of the Quarterly Report on Form 10-Q filed with the SEC on December 15, 2023).
3.4	Certificate of Amendment to the Certificate of Incorporation, filed with the Delaware Secretary of State on October 27, 2023 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on October 30, 2023).
3.5	Amended and Restated Certificate of Designations of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, filed with the Delaware Secretary of State on March 1, 2024 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on March 7, 2024).
3.6	Certificate of Amendment to the Amended and Restated Certificate of Designations of Preferences, Rights and Limitations of Series B Convertible Preferred Stock, filed with the Delaware Secretary of State on March 21, 2024 (incorporated by reference to Exhibit 3.1 of the Current Report on Form 8-K filed with the SEC on March 22, 2024).
3.7	Certificate of Designations of Preferences and Rights of Series A Preferred Stock, as filed with the Delaware Secretary of State on May 9, 2024 (incorporated by reference to Exhibit 3.1 of the amended Current Report on Form 8-K/A filed with the SEC on May 10, 2024).
3.8	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 of the registration statement on Form S-1 filed with the SEC on May 10, 2021).
4.1	Form of Warrant issued to Ault Lending, LLC (formerly, Digital Power Lending, LLC), dated March 9, 2021 (incorporated by reference to Exhibit 3.1 of Form 1-U filed with the SEC on March 12, 2021).
4.2	Form of Warrant (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on February 2, 2024).
4.3	Form of Warrant (incorporated by reference to Exhibit 4.1 of the Current Report on Form 8-K filed with the SEC on May 9, 2024).
4.4*	Description of Capital Stock.
10.1	Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., dated May 1, 2016 (incorporated by reference to Exhibit 6.1 of Form DOS/A filed with the SEC on September 29, 2016).
10.2	Standard Exclusive License Agreement with Sublicensing Terms Number LIC18110 with the University of South Florida Research Foundation, Inc., dated July 2, 2018 (incorporated by reference to Exhibit 6.3 of Form 1-K filed with the SEC on February 21, 2019).
10.3	Standard Exclusive License Agreement with Sublicensing Terms Number LIC18111 with the University of South Florida Research Foundation, Inc., dated July 2, 2018 (incorporated by reference to Exhibit 6.4 of Form 1-K filed with the SEC on February 21, 2019).
10.4	Standard Exclusive License Agreement with Sublicensing Terms Number LIC19050 with the University of South Florida Research Foundation, Inc., dated June 10, 2020 (incorporated by reference to Exhibit 6.6 of Form 1-K filed with the SEC on August 28, 2020).
10.5	Standard Exclusive License Agreement with Sublicensing Terms Number LIC19051 with the University of South Florida Research Foundation, Inc., dated June 10, 2020 (incorporated by reference to Exhibit 6.7 of Form 1-K filed with the SEC on August 28, 2020).
10.6+	2016 Amended and Restated Stock Incentive Plan (incorporated by reference to Exhibit 99.1 of Form S-8 filed with the SEC on July 13, 2021).
10.7+	2021 Stock Incentive Plan (incorporated by reference to Exhibit 99.2 of Form S-8 filed with the SEC on July 13, 2021).
10.8	Form of Amendment to Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., dated April 16, 2023 (incorporated by reference to Exhibit 10.13 of annual report on Form 10-K filed with the SEC on July 27, 2023).
10.9	Form of Amendment to Standard Exclusive License Agreement with Sublicensing Terms Number LIC19050 with the University of South Florida Research Foundation, Inc., dated April 16, 2023 (incorporated by reference to Exhibit 10.14 of annual report on Form 10-K filed with the SEC on July 27, 2023).
10.10	Form of Amendment to Standard Exclusive License Agreement with Sublicensing Terms Number LIC19051 with the University of South Florida Research Foundation, Inc., dated April 16, 2023 (incorporated by reference to Exhibit 10.15 of annual report on Form 10-K filed with the SEC on July 27, 2023).

10.11	Form of Amendment to Standard Exclusive License Agreement with Sublicensing Terms Number LIC18110 with the University of South Florida Research Foundation, Inc., dated June 8, 2023 (incorporated by reference to Exhibit 10.16 of annual report on Form 10-K filed with the SEC on July 27, 2023).
10.12	Form of Amendment to Standard Exclusive License Agreement with Sublicensing Terms Number LIC18111 with the University of South Florida Research Foundation, Inc., dated June 8, 2023 (incorporated by reference to Exhibit 10.17 of annual report on Form 10-K filed with the SEC on July 27, 2023).
10.13	Securities Purchase Agreement, dated January 31, 2024 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on February 2, 2024).
10.14	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K filed with the SEC on May 9, 2024).
10.15	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K filed with the SEC on May 9, 2024).
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 of the registration statement on Form S-1 filed with the SEC on June 3, 2024).
23.1*	Consent of Haskell & White LLP, Independent Registered Public Accounting Firm.
23.2*	Consent of Baker Tilly US, LLP, Independent Registered Public Accounting Firm.
24.1*	Power of Attorney. Reference is made to the signature page hereto.
31.1*	Certification of Chief Executive Officer required by Rule 13a-14(a) or Rule 15d-14(a).
31.2*	Certification of Chief Financial Officer required by Rule 13a-14(a) or Rule 15d-14(a).
32.1**	Certification of Chief Executive and Financial Officer required by Rule 13a-14(b) or Rule 15d-14(b) and Section 1350 of Chapter 63 of Title 18 of the United States Code.
97.1*	Alzamend Neuro, Inc., Clawback Policy.
101.INS*	Inline XBRL Instance Document. The instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

*Filed herewith.
** This certification will not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liability of that section. Such certification will not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Exchange Act, except to the extent specifically incorporated by reference into such filing.
+ Indicates management contract or compensatory plan.

ITEM 16. FORM 10–K SUMMARY

None.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

ALZAMEND NEURO, INC.

Date: July 30, 2024

By: /s/ Stephan Jackman
Stephan Jackman
Chief Executive Officer (principal executive officer)

Date: July 30, 2024

By: /s/ David J. Katzoff
David J. Katzoff
Chief Financial Officer (principal financial and accounting officer)

POWER OF ATTORNEY

KNOW ALL BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Stephan Jackman and David J. Katzoff, and each of them, as his or her true and lawful attorneys-in-fact and agents, each with the full power of substitution, for him or her and in his or her name, place or stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on in the capacities and on the dates indicated.

Name	Title	Date
By: /s/ Stephan Jackman Stephan Jackman	Chief Executive Officer and Director (principal executive officer)	July 30, 2024
By: /s/ David J. Katzoff David J. Katzoff	Chief Financial Officer (principal financial and accounting officer)	July 30, 2024
By: /s/ William B. Horne William B. Horne	Chairman of the Board	July 30, 2024
By: /s/ Henry Nisser Henry Nisser	Executive Vice President, General Counsel and Director	July 30, 2024
By: /s/ Mark Gustafson Mark Gustafson	Director	July 30, 2024
By: /s/ Lynne Fahey McGrath, M.P.H., Ph.D. Lynne Fahey McGrath, M.P.H., Ph.D.	Director	July 30, 2024
By: /s/ Andrew H. Woo, M.D., Ph.D. Andrew H. Woo, M.D., Ph.D	Director	July 30, 2024
By: /s/ Jeffrey Oram Jeffrey Oram	Director	July 30, 2024

INDEX TO FINANCIAL STATEMENTS

ALZAMEND NEURO, INC.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders
Alzamend Neuro, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Alzamend Neuro, Inc. (the "Company") as of April 30, 2024, and the related statements of operations, changes in stockholders' equity, and cash flows for the year then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of April 30, 2024, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses from operations, negative cash flow from operations and is dependent on additional financing to fund current and future operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2 to the financial statements. The financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provides a reasonable basis for our opinion.

HASKELL & WHITE LLP

We have served as the Company's auditor since 2024.

Irvine, California
July 30, 2024

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Alzamend Neuro, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheet of Alzamend Neuro, Inc. (the "Company") as of April 30, 2023, the related statements of operations, stockholders' equity, and cash flows, for the year ended April 30, 2023, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of April 30, 2023, and the results of its operations and its cash flows for the year ended April 30, 2023, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has recurring losses from operations, negative cash flow from operations and is dependent on additional financing to

fund current and future operations. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans regarding these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BAKER TILLY US, LLP

We served as the Company’s auditor from 2019 to 2024

San Diego, California
July 27, 2023, except for the effects of the reverse stock splits described in Note 1, as to which the date is July 30, 2024

ALZAMEND NEURO, INC.
Balance Sheets

	April 30, 2024	April 30, 2023
ASSETS		
CURRENT ASSETS		
Cash	$ 376,048	$ 5,140,859
Prepaid expenses and other current assets	79,194	447,589
Prepaid expenses - related party	-	247,334
TOTAL CURRENT ASSETS	455,242	5,835,782
Property, plant and equipment, net	176,346	79,843
TOTAL ASSETS	$ 631,588	$ 5,915,625
LIABILITIES AND STOCKHOLDERS’ (DEFICIT) EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued liabilities	$ 2,925,059	$ 2,870,122
Note payable	300,714	-
TOTAL LIABILITIES, ALL CURRENT	3,225,773	2,870,122
COMMITMENTS AND CONTINGENCIES		
STOCKHOLDERS’ (DEFICIT) EQUITY		
Series B Convertible Preferred Stock, $ 0.0001 stated value per share, 6,000 designated; 2,100 and nil issued and outstanding as of April 30, 2024 and April 30, 2023, respectively	-	-
Common stock, $ 0.0001 par value: 300,000,000 shares authorized; 687,999 and 646,267 issued and outstanding as of April 30, 2024 and April 30, 2023, respectively	69	65
Additional paid-in capital	51,426,154	62,001,395
Note receivable for common stock – related party	-	(14,883,295)
Accumulated deficit	(54,020,408)	(44,072,662)
TOTAL STOCKHOLDERS’ (DEFICIT) EQUITY	(2,594,185)	3,045,503
TOTAL LIABILITIES AND STOCKHOLDERS’ (DEFICIT) EQUITY	$ 631,588	$ 5,915,625

The accompanying notes are an integral part of these financial statements.

ALZAMEND NEURO, INC.
Statements of Operations

For the Year Ended April 30,

	2024	2023
OPERATING EXPENSES		
Research and development	$ 6,455,107	$ 7,445,857
General and administrative	3,482,538	7,424,609
Total operating expenses	9,937,645	14,870,466
Loss from operations	(9,937,645)	(14,870,466)
OTHER INCOME (EXPENSE), NET		
Interest expense	(10,101)	(7,701)
Total other income (expense), net	(10,101)	(7,701)
NET LOSS	$ (9,947,746)	$ (14,878,167)
Basic and diluted net loss per common share	$ (14.70)	$ (22.89)
Basic and diluted weighted average common shares outstanding	676,565	650,126

The accompanying notes are an integral part of these financial statements.

ALZAMEND NEURO, INC.
Statements of Changes in Stockholders' Equity (Deficit)
For the Years Ended April 30, 2024 and April 30, 2023

	Series B Convertible Preferred Stock		Common Stock		Additional Paid-In	Note Receivable for Common Stock -	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Related Party	Deficit	Total
BALANCES, April 30, 2022	-	$ -	636,545	$ 64	$57,429,237	$ (14,883,295)	$ (29,194,495)	$13,351,511
Issuance of common stock for restricted stock awards	-	-	167	-	-	-	-	-
Stock-based compensation to employees and consultants	-	-	-	-	3,582,625	-	-	3,582,625
Proceeds from stock option exercise	-	-	3,333	-	200	-	-	200
Issuance of common stock for related party payable	-	-	6,222	1	989,333	-	-	989,334
Net loss	-	-	-	-	-	-	(14,878,167)	(14,878,167)
BALANCES, April 30, 2023	-	$ -	646,267	$ 65	$62,001,395	$ (14,883,295)	$ (44,072,662)	$ 3,045,503
Issuance of common stock for cash	-	-	107,682	11	1,252,414	-	-	1,252,425
Issuance of common stock for restricted stock awards	-	-	167	-	-	-	-	-
Issuance of preferred stock for cash	2,100	-	-	-	2,100,000	-	-	2,100,000
Subscription receivable payment received	-	-	-	-	(7,002)	7,002	-	-
Return of common stock for subscription receivable	-	-	(66,117)	(7)	(14,876,286)	14,876,293	-	-
Stock-based compensation to employees and consultants	-	-	-	-	955,633	-	-	955,633
Net loss	-	-	-	-	-	-	(9,947,746)	(9,947,746)
BALANCES, April 30, 2024	2,100	$ -	687,999	$ 69	$51,426,154	$ -	$ (54,020,408)	$ (2,594,185)

The accompanying notes are an integral part of these financial statements.

ALZAMEND NEURO, INC.
Statements of Cash Flows

	For the Year Ended April 30, 2024	2023
Cash flows from operating activities:		
Net loss	$ (9,947,746)	$ (14,878,167)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	50,740	23,066
Interest expense - debt discount	714	-
Stock-based compensation to employees and consultants	955,633	3,582,625
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	368,395	(97,866)

Prepaid expenses related party	247,334	739,918
Accounts payable and accrued liabilities	54,937	1,707,272
Net cash used in operating activities	(8,269,993)	(8,923,152)
Cash flows from investing activities:		
Purchase of equipment	(147,243)	-
Net cash used in investing activities	(147,243)	-
Cash flows from financing activities:		
Proceeds from the issuance of common stock, net	1,252,425	-
Proceeds from stock option exercise	-	200
Proceeds from the issuance of note payable	300,000	-
Proceeds from the issuance of preferred stock - related party	2,100,000	-
Net cash provided by financing activities	3,652,425	200
Net decrease in cash	(4,764,811)	(8,922,952)
Cash at beginning of period	5,140,859	14,063,811
Cash at end of period	$ 376,048	$ 5,140,859
Supplemental disclosures of cash flow information:		
Non-cash financing activities:		
Return of common stock for cancellation of subscription receivable	$ (14,883,295)	$ -
Debt discount from issuance of note payable	$ 10,000	$ -
Fair value of warrants issued in connection with preferred stock related party	$ 1,902,140	$ -
Issuance of common stock for related party payable	$ -	$ 989,334

The accompanying notes are an integral part of these financial statements.

ALZAMEND NEURO, INC.
NOTES TO FINANCIAL STATEMENTS

1. DESCRIPTION OF BUSINESS

Organization

Alzamend Neuro, Inc. (the "Company" or "Alzamend"), is a clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer's disease ("Alzheimer's"), bipolar disorder ("BD"), major depressive disorder ("MDD") and post-traumatic stress disorder ("PTSD"). With two current product candidates, Alzamend aims to bring treatments or cures to market at a reasonable cost as quickly as possible. The Company's current pipeline consists of two novel therapeutic drug candidates: (i) a patented ionic cocrystal technology delivering a therapeutic combination of lithium, proline and salicylate, known as AL001, through two royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc., as licensor (the "Licensor"); and (ii) a patented method using a mutant peptide sensitized cell as a cell-based therapeutic vaccine that seeks to restore the ability of a patient's immunological system to combat Alzheimer's, known as ALZN002, through a royalty-bearing exclusive worldwide license from the same Licensor.

The Company is devoting substantially all its efforts towards research and development of its two product candidates and raising capital. The Company has not generated any product revenue to date. The Company has financed its operations to date primarily through debt financings and through the sale of its common stock, par value $ 0.0001 per share ("Common Stock") and its preferred stock, par value $ 0.0001 per share. The Company expects to continue to incur net losses in the foreseeable future.

Reverse Stock Splits

On October 27, 2023, pursuant to the authorization provided by the Company's stockholders at a special meeting of stockholders, the Company filed an amendment to the Certificate of Incorporation to effectuate a reverse stock split of the Company's issued and outstanding Common Stock by a ratio of one-for-fifteen (the "First Reverse Split"). The First Reverse Split did not affect the number of authorized shares of Common Stock, preferred stock or their respective par value per share. As a result of the First Reverse Split, each fifteen shares of Common Stock issued and outstanding prior to the First Reverse Split were converted into one share of Common Stock. The First Reverse Split became effective in the State of Delaware on October 31, 2023. All share amounts in these financial statements have been updated for all periods presented to reflect the First Reverse Split.

On July 10, 2024, pursuant to the authorization provided by the Company's stockholders at its annual meeting of stockholders, the Company filed an amendment to the Certificate of Incorporation to effectuate a reverse stock split of the Company's issued and outstanding Common Stock by a ratio of one-for-ten (the "Second Reverse Split"). The Second Reverse Split did not affect the number of authorized shares of Common Stock, preferred stock or their respective par value per share. As a result of the Second Reverse Split, each ten shares of Common Stock issued and outstanding prior to the Second Reverse Split were converted into one share of Common Stock. The Second Reverse Split became effective in the State of Delaware on July 16, 2024. All share amounts in these financial statements have been updated for all periods presented to reflect the Second Reverse Split.

2. LIQUIDITY, GOING CONCERN AND MANAGEMENT'S PLANS

The accompanying financial statements have been prepared on the basis that the Company will continue as a going concern. As of April 30, 2024, the Company had cash of $ 376,000 and an accumulated deficit of $ 54.0 million. For the year ended April 30, 2024, the Company had a net loss of $ 9.9 million and cash used in operating activities of $ 8.3 million. The Company had cash as of April 30, 2023, totaling $ 5.1 million and accumulated deficit of $ 44.1 million. In the past, the Company has financed its operations principally through issuances of equity and debt instruments.

On January 31, 2024, the Company and Ault Lending, LLC ("Ault Lending"), entered into a securities purchase agreement (the "AL SPA") for the purchase of up to 6,000 shares of Series B Convertible Preferred Stock and warrants to purchase shares up to 600,000 shares of Common Stock. The AL SPA provides that Ault Lending may purchase up to $6 million of Series B Convertible Preferred Stock in one or more closings. Ault Lending has the right to purchase up to $2 million of Series B Convertible Preferred Stock, on or before March 31, 2024, and the right to purchase up to $4 million of Series B Convertible Preferred Stock after March 31, 2024, but on or before March 31, 2025 (the "Termination Date"). The Agreement will automatically terminate if the final closing has not occurred prior to the Termination Date.

On January 31, 2024, the Company sold 1,220 shares of Series B Convertible Preferred Stock and warrants to purchase 122,000 shares of Common Stock with an exercise price of $ 12.00 , for a total purchase price of $ 1.22 million. The purchase price was paid by the cancellation of $ 1.15 million of cash advances made by Ault Lending to the Company between November 9, 2023 and January 31, 2024 and a subscription receivable of $ 70,000 .

On March 26, 2024, the Company sold 780 shares of Series B Convertible Preferred Stock and warrants to purchase 78,000 shares of Common Stock with an exercise price of $ 12.00 , for a total purchase price of $ 780,000 .

On April 29, 2024, the Company sold 100 shares of Series B Convertible Preferred Stock and warrants to purchase 10,000 shares of Common Stock with an exercise price of $ 12.00 , for a total purchase price of $ 100,000 .

On May 8, 2024, the Company and Orchid Finance, LLC (“Orchid”) , entered into a securities purchase agreement (the “Orchid SPA”) for the purchase of up to 2,500 shares of Series A Convertible Preferred Stock and warrants to purchase shares up to 2,500,000 shares of Common Stock in several tranche closings.

On May 10, 2024, the Company sold 100 shares of Series A Convertible Preferred Stock and warrants to purchase 80,000 shares of Common Stock with an exercise price of $ 12.50 , for a total purchase price of $ 1.0 million. The purchase price was paid by the surrender and cancellation of a term note issued by the Company to Orchid of $ 311,356 , consisting of $ 310,000 of principal and $ 1,356 of accrued and unpaid interest, $ 100,000 discount and net cash of $ 588,644 .

On June 25, 2024, the Company sold 150 shares of Series A Convertible Preferred Stock and warrants to purchase 120,000 shares of Common Stock with an exercise price of $ 12.50 , for a total purchase price of $ 1.5 million. The purchase price was paid in cash.

The Company expects to continue to incur losses for the foreseeable future and needs to raise additional capital until it is able to generate revenues from operations sufficient to fund its development and commercial operations. These factors create substantial doubt about our ability to continue as a going concern. However, based on the Company’s current business plan, management believes that the Company’s cash and cash equivalents at April 30, 2024, together with the anticipated receipt of funds from its Series A and Series B Convertible Preferred Stock securities purchase agreements, will be sufficient to meet the Company’s anticipated cash requirements during the twelve-month period subsequent to the issuance of the financial statements included in this Annual Report.

3. SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“U.S. GAAP”) and pursuant to the rules and regulations of the Securities and Exchange Commission (the “Commission”).

Accounting Estimates

The preparation of financial statements, in conformity with U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company’s critical accounting policies that involve significant judgment and estimates include research and development, stock-based compensation, warrant valuation, and valuation of deferred income taxes. Actual results could differ from those estimates.

Cash and Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity of three months or less when purchased to be cash equivalents. As of April 30, 2024 and 2023, the Company had no cash equivalents.

Fair Value of Financial Instruments

Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 820, *Fair Value Measurement*, defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 assumptions: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities including liabilities resulting from imbedded derivatives associated with certain warrants to purchase common stock.

The fair values of warrants issued in connection with equity or debt issuance are determined using the Black-Scholes valuation model, a “Level 3” fair value measurement, based on the estimated fair value of the underlying common stock, volatility based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities, the expected life based on the remaining contractual term of the conversion option and warrants and the risk free interest rate based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the warrants’ contractual life.

Income Taxes

The Company determines its income taxes under the asset and liability method. Under the asset and liability approach, deferred income tax assets and liabilities are calculated and recorded based upon the future tax consequences of temporary differences by applying enacted statutory tax rates applicable to future periods for differences between the financial statements carrying amounts and the tax basis of existing assets and liabilities. Generally, deferred income taxes are classified as current or non-current in accordance with the classification of the related asset or liability. Those not related to an asset or a liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse. Valuation allowances are provided for significant deferred income tax assets when it is more likely than not that some or all of the deferred tax assets will not be realized. As of April 30, 2024, the Company had fully reserved the net deferred income tax assets by taking a full valuation allowance

against these assets.

The Company recognizes tax liabilities by prescribing a minimum probability threshold that a tax position must meet before a financial statement benefit is recognized and also provides guidance on de-recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The minimum threshold is defined as a tax position that is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than 50% likely of being realized upon ultimate settlement. To the extent that the final tax outcome of these matters is different than the amount recorded, such differences impact income tax expense in the period in which such determination is made. Interest and penalties, if any, related to accrued liabilities for potential tax assessments are included in income tax expense. U.S. GAAP also requires management to evaluate tax positions taken by the Company and recognize a liability if the Company has taken uncertain tax positions that more likely than not would not be sustained upon examination by applicable taxing authorities. Management of the Company has evaluated tax positions taken by the Company and has concluded that as of April 30, 2024, there were no uncertain tax positions taken, or expected to be taken, that would require recognition of a liability that would require disclosure in the financial statements.

Research and Development Expenses

Research and development costs are expensed as incurred. Research and development costs consist of scientific consulting fees and lab supplies, as well as fees paid to clinical research organizations that conduct certain research and development activities on behalf of the Company.

The Company has acquired and may continue to acquire the rights to develop and commercialize new product candidates from third parties. The upfront payments to acquire licenses, products or rights, as well as any future milestone payments, are immediately recognized as research and development expense provided that there is no alternative future use of the rights in other research and development projects.

Stock-Based Compensation

The Company recognizes stock-based compensation expense for stock options on a straight-line basis over the requisite service period and accounts for forfeitures as they occur. The Company's stock-based compensation costs are based upon the grant date fair value of options estimated using the Black-Scholes option pricing model. To the extent any stock option grants are made subject to the achievement of a performance-based milestone, management evaluates when the achievement of any such performance-based milestone is probable based on the satisfaction of the performance conditions as of the reporting date.

The Company recognizes stock-based compensation expense for restricted stock on a straight-line basis over the requisite service period and accounts for forfeitures as they occur. The Company's stock-based compensation for restricted stock is based upon the estimated fair value of the Common Stock on the date of grant.

The Black-Scholes option pricing model utilizes inputs which are highly subjective assumptions and generally requires significant judgment. Certain of such assumptions involve inherent uncertainties and the application of significant judgment. As a result, if factors or expected outcomes change and the Company uses significantly different assumptions or estimates, the Company's stock-based compensation could be materially different.

Warrants

The Company accounts for stock warrants as either equity instruments, derivative liabilities, or liabilities in accordance with ASC 480, *Distinguishing Liabilities from Equity* ("ASC 480") and ASC 815, *Derivatives and Hedging* ("ASC 815"), depending on the specific terms of the warrant agreement.

During the year ended April 30, 2024, based on the terms of the Company's warrant agreements, the Company accounted for the warrants as equity instruments as the warrants were indexed to the Common Stock, required settlement in shares and would be classified as equity under ASC 815.

Loss per Common Share

The Company utilizes FASB ASC Topic No. 260, *Earnings per Share*. Basic loss per share is computed by dividing loss available to common stockholders by the weighted-average number of common shares outstanding. Diluted loss per share is computed similarly to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the additional common shares had been issued and if such common shares were dilutive. Diluted loss per common share reflects the potential dilution that could occur if options, restricted stock units and warrants were to be exercised or converted or otherwise resulted in the issuance of Common Stock that then shared in the earnings of the entity.

Since the effects of outstanding options, restricted stock units and warrants are anti-dilutive in the periods presented, shares of Common Stock underlying these instruments have been excluded from the computation of loss per common share.

The following sets forth the number of shares of Common Stock underlying outstanding options and warrants that have been excluded from the computation of loss per common share:

	For the Year Ended April 30,	
	2024	**2023**
Stock options (1)	120,333	121,055
Restricted stock units	167	333
Warrants	240,449	67,665
	360,949	189,053

(1) The Company has excluded 10,000 stock options for the years ended April 30, 2024 and 2023, respectively, with an exercise price of $0.06, from its anti-dilutive securities as these shares have been included in our determination of basic loss per share as they represent shares issuable for little or no cash consideration upon the satisfaction of certain conditions pursuant to ASC 260-10-45-14.

Preferred Stock Classification

The Company analyzes the terms of its preferred stock using ASC Topic No. 480, *Distinguishing Liabilities from Equity*, to determine whether the Company's preferred stock should be classified as a liability or equity, and if classified as equity, permanent or temporary. Common criteria the Company considers are redemption provisions, conversion options, cumulative of mandatory fixed dividends, discretionary dividends based on earning, voting rights and collateral requirements.

4. NOTE RECEIVABLE, RELATED PARTY, NET

On April 30, 2019, the Company and Ault Life Science Fund, LLC ("ALSF"), a related party, entered into a securities purchase agreement for the purchase of 66,667 shares of Common Stock for a total purchase price of $ 15,000,000 , or $225.00 per share with 33,333 warrants with a 5 -year life and an exercise price of $ 450.00 per share and vesting upon issuance (the "ALSF Warrants"). The total purchase price of $15,000,000 was in the form of a non-interest-bearing note receivable with a 12 -month term from ALSF. In November 2019, the term of the note receivable was extended to December 31, 2021, and in May 2021, the term of the note receivable was extended to December 31, 2023. The note was secured by a pledge of the purchased shares. As the note receivable from ALSF was related to the issuance of Common Stock, it is recorded as an offset to additional paid-in capital. ALSF is wholly owned by Ault Life Sciences, Inc. ("ALSI"). ALSI is majority owned by Ault & Company, Inc. ("Ault & Co."). Messrs. Ault, Horne and Nisser, directors of the Company, are also directors of Ault & Co.

On January 19, 2024, the Company and ALSF entered into a settlement agreement and release of claims whereby ALSF returned to the Company 66,117 shares of Common Stock and the ALSF Warrants for settlement of the outstanding balance of the note receivable in the amount of $ 14,876,293 .

5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets were as follows:

	April 30, 2024	April 30, 2023
Prepaid clinical trial fees	$ -	$ 352,635
Prepaid insurance	60,522	92,154
Other prepaid expenses	18,672	2,800
Total prepaid expenses and other current assets	$ 79,194	$ 447,589

On June 14, 2023, the Company purchased directors' and officers' insurance for 12 months in the amount of $ 337,000 . Prepaid insurance at April 30, 2024 represented the unamortized portion of directors' and officers' insurance.

6. INCOME TAXES

The following is a geographical breakdown of the Company's loss before the provision for income taxes:

	April 30, 2024	April 30, 2023
Pre-tax loss:		
Federal	$ (9,947,746)	$ (14,878,167)
Total pre-tax loss	$ (9,947,746)	$ (14,878,167)

Significant components of the Company's deferred tax assets were as follows:

	April 30, 2024	April 30, 2023
Deferred income tax asset:		
Accruals	$ -	$ 241,500
Capitalized research expenditures	2,321,972	1,426,779
Net operating loss carryover	10,838,412	6,885,428
Stock-based compensation	2,638,820	2,276,109
Total deferred tax asset	15,799,204	10,829,816
Fixed assets	(32,400)	(16,767)
Valuation allowance	(15,766,804)	(10,813,049)
Deferred income tax asset, net of allowance	$ -	$ -

A reconciliation of the federal statutory income tax rate to the Company's effective income tax rate for the years ended April 30, 2024 and 2023, is as follows:

	2024	2023
Tax benefit at U.S. Federal statutory tax rate	21.0%	21.0%
State income tax, net of federal benefit	28.9%	- 18.3%
Increase (decrease) in tax rate resulting from:		
Change in valuation allowance	- 49.8%	- 4.8%
Stock-based compensation	- 0.1%	0.3%
Other	0.0%	2.0%
Effective tax rate	0.0%	0.0%

In assessing the realization of deferred tax assets, management considers whether it is more likely than not the Company's deferred tax assets will be realized. Management considers the scheduled reversal of deferred tax assets, projected future taxable income and tax planning strategies in making such assessments. Given historical generation of and expected future taxable losses, management determined it is more likely than not that some or all of the deferred tax assets will not be realized. Therefore, a full valuation allowance was maintained, as of the years ended April 30, 2024 and 2023, of $ 15,766,804 and $ 10,813,049 , respectively.

At April 30, 2024, the Company maintained U.S. Federal and state net operating loss ("NOL") carryovers of approximately $ 38,716,141 and $ 190,584,088 respectively. Federal and state NOLs begin to expire in various years depending on relevant jurisdiction. In accordance with Internal Revenue Code §382 ("IRC §382"), the future deductibility of the Company's NOL's may be subject to an annual limitation in the event of a change in control as defined by applicable regulations. The Company has yet to complete a formal study to confirm NOL's are not limited in utilization per IRC §382 and may reduce applicable deferred tax assets upon completion of such a study, in future periods.

The impact of an uncertain income tax position on the income tax return must be recognized at the largest amount that is more likely than not to be sustained upon audit by the relevant taxing authority. An uncertain income tax position will not be recognized if it has less than a 50% likelihood of being sustained. The Company had no uncertain tax positions as of April 30, 2024.

The Company's policy is to recognize interest and penalties related to income tax matters in the provision for income taxes. As of April 30, 2024, no interest or penalties have been recorded pertaining to uncertain tax positions.

The Company is subject to taxation in the United States and various U.S. state jurisdictions. All tax years remain open to examination by the Internal Revenue Service and relevant state authorities.

On December 27, 2020, the Consolidated Appropriations Act, 2021 ("CAA 2021"), which included a number of provisions including, but not limited to, the extension of numerous employment tax credits, the extension of the Section 179D deduction, enhanced business meals deductions, and the deductibility of expenses paid with Paycheck Protection Program loan funds that are forgiven, was signed into law. Accordingly, the effects of the CAA 2021 have been incorporated into the income tax provision for the year ended April 30, 2024. These provisions did not have a material impact on the income tax provision.

7. STOCK-BASED COMPENSATION

2016 Stock Incentive Plan

On April 30, 2016, the Company's stockholders approved the Company's 2016 Stock Incentive Plan (the "Plan"). The Plan provides for the issuance of a maximum of 83,333 shares of common stock to be offered to the Company's directors, officers, employees, and consultants. On March 1, 2019, the Company's stockholders approved an additional 50,000 shares to be available for issuance under the Plan. Options granted under the Plan have an exercise price equal to or greater than the fair value of the underlying common stock at the date of grant and become exercisable based on a vesting schedule determined at the date of grant. The options expire between five and 10 years from the date of grant. Restricted stock awards granted under the Plan are subject to a vesting period determined at the date of grant.

2021 Stock Incentive Plan

In February 2021, the Company's board of directors (the "Board") adopted, and the stockholders approved, the Alzamend Neuro, Inc. 2021 Stock Incentive Plan (the "2021 Plan"). The 2021 Plan authorizes the grant to eligible individuals of (1) stock options (incentive and non-statutory), (2) restricted stock, (3) stock appreciation rights, or SARs, (4) restricted stock units, and (5) other stock-based compensation.

Stock Subject to the 2021 Plan. The maximum number of shares of common stock that may be issued under the 2021 Plan is 66,667 shares, which number will be increased to the extent that compensation granted under the 2021 Plan is forfeited, expires or is settled for cash (except as otherwise provided in the 2021 Plan). Substitute awards (awards made or shares issued by the Company in assumption of, or in substitution or exchange for, awards previously granted, or the right or obligation to make future awards, in each case by a company that the Company acquires or any subsidiary of the Company or with which the Company or any subsidiary combines) will not reduce the shares authorized for grant under the 2021 Plan, nor will shares subject to a substitute award be added to the shares available for issuance or transfer under the 2021 Plan.

Restricted Stock. In May 2021, the Company issued restricted stock awards pursuant to the 2021 Plan to one employee and four independent Board members. The restricted stock awards vest over 48 months for the employee and 12 months for the independent Board members. The awards require continued service to the Company during the vesting period. The vesting provisions of individual awards may vary as approved by the Board. Compensation expense for restricted stock is generally recorded based on its market value on the date of grant and recognized ratably over the associated service and performance period.

Stock Options. All options that the Company grants are granted at the per share fair value on the grant date. Vesting of options differs based on the terms of each option. The Company has valued the options at their date of grant utilizing the Black Scholes option pricing model. As of the date of issuance of these options, there was not an active public market for the Company's shares. Accordingly, the fair value of the underlying options was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. The risk-free interest rate used in the calculations is based on the implied yield available on U.S. Treasury issues with an equivalent term approximating the expected life of the options as calculated using the simplified method. The expected life of the options used was based on the contractual life of the option granted. Stock-based compensation is a non-cash expense because the Company settles these obligations by issuing shares of common stock from its authorized shares instead of settling such obligations with cash payments.

A summary of stock option activity for the year ended April 30, 2024, is presented below:

		Outstanding Options			
	Shares Available for Grant	Number of Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
Balance at April 30, 2023	61,278	98,722	$ 182.31	6.18	$ 819,900
Options granted	-	-	$ -		
Options exercised	-	-	$ -		
Options cancelled/forfeited	722	(722)	$ 750.00		
Balance at April 30, 2024	62,000	98,000	$ 178.12	5.22	$ 70,500
Options vested and expected to vest at April 30, 2024		91,334	$ 178.31	4.98	$ 70,500
Options exercisable at April 30, 2024		90,208	$ 177.51	4.94	$ 70,500

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (i.e., the difference between the estimated fair value on the respective date and the exercise price, times the number of shares) that would have been received by the option holders had all option holders exercised their options.

Restricted stock unit activity for the year ended April 30, 2024 is presented below:

	Shares	Weighted Average Grant Date Fair Value
Unvested at April 30, 2023	333	$ 375.00

Granted	-		-
Vested	(166)		375.00
Cancelled	-		-
Unvested at April 30, 2024	167	$	375.00

Stock Options Granted to Employees and Consultants

The estimated fair value of stock options granted to employees and consultants during the year ended April 30, 2023 were calculated using the Black-Scholes option-pricing model using the following assumptions:

	For the Year Ended April 30, 2023
Expected term (in years)	6.25
Volatility	88.94 %
Risk-free interest rate	3.89 %
Dividend yield	0.0 %

Expected Term: The expected term represents the period that the options granted are expected to be outstanding and is determined using the simplified method (based on the mid-point between the vesting date and the end of the contractual term).

Expected Volatility: The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company only has a limited trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate: The Company based the risk-free interest rate over the expected term of the options based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

Expected Dividend: The Company has not paid and does not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

There were no stock options granted during the year ended April 30, 2024.

For the year ended April 20, 2024 and 2023, stock-based compensation related to restricted stock grants and stock options were $ 956,000 and $ 3.6 million, respectively, for employees and directors.

Performance Contingent Stock Options Granted to Employee

On November 26, 2019, the Board granted 28,333 performance and market contingent awards to certain key employees and a director. These grants were made outside of the Plan. These awards have an exercise price of $225.00 per share. These awards have multiple separate market triggers for vesting based upon either (i) the successful achievement of stepped target closing prices on a national securities exchange for 90 consecutive trading days later than 180 days after the Company's initial public offering ("IPO") for its common stock, or (ii) stepped target prices for a change in control transaction. The target prices ranged from $1,500 per share to $6,000 per share. In the event any of the stock price milestones are not achieved within three years , the unvested portion of the performance options will be reduced by 25%.

On November 22, 2022, the Compensation Committee of the Board modified the performance criteria for these awards. The target price range is now $1,500 per share to $3,000 per share. Additionally, if the stock price milestones are now not achieved by November 27, 2026, as opposed to within three years, the unvested portion of the portion of the performance options will be reduced by 25%. Due to the significant risks and uncertainties associated with achieving the market-contingent awards, as of April 30, 2024, the Company believes that the achievement of the requisite performance conditions is not probable and, as a result, no compensation cost has been recognized for these awards.

On November 29, 2022, the Compensation Committee of the Board granted 13,333 performance-based stock option to the Chief Executive Officer at an exercise price of $175.50 per share, of which 50% vest upon the completion and announcement of topline data from the Company's Phase II clinical trial of AL001 within three years from grant date and the remaining 50% vest upon the completion and announcement of topline data from the Company's Phase II clinical trial of ALZN002 within four years from the grant date. During the year ended April 30, 2023, the Company believed that it was probable that the performance condition of the completion and announcement of topline data from the Company's Phase II clinical trial of AL001 would be achieved and had recognized the related stock-based compensation. As of April 30, 2024, the Company believed that the achievement of the second performance condition was not probable and, as a result, no compensation cost has been recognized related to Phase I/IIA of ALZN002.

Performance Contingent Stock Options Granted to TAMM Net

On March 23, 2021, the Company issued performance-based stock options to the certain team members at TAMM Net, Inc. ("TAMM Net") to purchase an aggregate of 3,000 shares of common stock at a per share exercise price of $225.00 per share, of which 50% vest upon the completion of Phase I of AL001 by March 31, 2022, and the remaining 50% vest upon completion of Phase I of ALZN002 by December 31, 2022. The performance goal of completing Phase I of AL001 was achieved on March 22, 2022.

On January 19, 2023, the Board modified the performance criteria for these awards. The remaining 50% of the grant would have vested upon the completion and announcement of topline data of the first cohort from a Phase I/IIA clinical trial of ALZN002 on/or before March 31, 2024. The modified performance criteria was not met on or before March 31, 2024 and, as a result, the remaining unvested stock options were cancelled and no compensation cost has been recognized for these awards related to ALZN002.

Performance Contingent Stock Options Granted to Consultants

On October 14, 2021, the Company issued performance-based stock options to two consultants to purchase an aggregate of 1,334 shares of Common Stock with an exercise price of $363.00 per share, of which 333 vest upon completion of each of the Phase II clinical trials of AL001 for a BD indication, AL001 for a PTSD indication, AL001 for an MDD indication and ALZN002 for an Alzheimer's indication.

On January 19, 2023, the Board modified the performance criteria for these awards. The revised grant will vest 25% if the Company (a) completes and announces topline data from a Phase II clinical trial of AL001 and ALZN002, as applicable, that would support a new drug application for the drug candidate and the indication listed below, and (b) obtained a "Study May Proceed" letter from the U.S. Food and Drug Administration ("FDA") for the additional Investigational New Drug ("IND") on/or before December 31, 2023, as follows: (i) AL001 – BD; (ii) AL001- MDD; (iii) AL001 – PTSD; and (iv)

ALZN002 – Alzheimer's.

During the year ended April 30, 2024, the Company filed INDs for BD, MDD and PTSD and received a "Study May Proceed" letter for BD in October 2023, MDD in November 2023 and PTSD in December 2023. As a result, 75% of the performance grant vested and the Company recognized stock-based compensation related to the vesting. As of April 30, 2024, the Company believed that the achievement of the remaining requisite performance condition was not probable and, as a result, no compensation cost has been recognized for these awards related to ALZN002 – Alzheimer's.

Stock-Based Compensation Expense

The Company's results of operations include expenses relating to stock-based compensation for the years ended April 30, 2024 and 2023, were comprised as follows:

	For the Year Ended April 30,	
	2024	2023
Research and development	$ 213,905	$ (42,589)
General and administrative	741,728	3,625,214
Total	$ 955,633	$ 3,582,625

As of April 30, 2024, total unamortized stock-based compensation expense related to unvested employee and non-employee awards that are expected to vest was $ 353,000 . The weighted-average period over which such stock-based compensation expense will be recognized is approximately 1.3 years.

8. WARRANTS

Warrant Issuances During 2024

During the year ended April 30, 2024, the Company issued warrants to purchase an aggregate of 210,000 shares of common stock at an exercise price of $ 12.00 per share.

(i) On January 31, 2024, the Company issued a warrant to purchase 122,000 shares of Common Stock at an exercise price of $ 12.00 in connection with the sale of convertible preferred stock to Ault Lending for $ 1,220,000 . Based on the terms of the Company's warrant agreement, the Company accounted for the warrant as an equity instrument as the warrant is indexed to the common stock, requires settlement in shares and would be classified as equity under ASC 815.

(ii) On March 26, 2024, the Company issued a warrant to purchase 78,000 shares of Common Stock at an exercise price of $ 12.00 in connection with the sale of convertible preferred stock to Ault Lending for $ 780,000 . Based on the terms of the Company's warrant agreement, the Company accounted for the warrant as an equity instrument as the warrant is indexed to the common stock, requires settlement in shares and would be classified as equity under ASC 815.

(iii) On April 29, 2024, the Company issued a warrant to purchase 10,000 shares of Common Stock at an exercise price of $ 12.00 in connection with the sale of convertible preferred stock to Ault Lending for $ 100,000 . Based on the terms of the Company's warrant agreement, the Company accounted for the warrant as an equity instrument as the warrant is indexed to the common stock, requires settlement in shares and would be classified as equity under ASC 815.

The following table summarizes information about common stock warrants at April 30, 2024:

Outstanding				Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
$12.00	210,000	5.3	$ 12.00	-	-
$262.50	1,076	0.5	$ 262.50	1,076	$ 262.50
$450.00	28,965	1.9	$ 450.00	28,965	$ 450.00
$937.50	408	2.1	$ 937.50	408	$ 937.50
$ 12.00 - $ 937.50	240,449	4.9	$ 67.45	30,449	$ 449.91

Warrant activity for the year ended April 30, 2024 is presented below:

	Number Outstanding	Weighted Average Exercise Price
Outstanding at April 30, 2023	67,662	$ 435.18
Granted	210,000	$ 12.00
Cancelled/Expired	(37,213)	$ 423.13
Outstanding at April 30, 2024	240,449	$ 67.45

The estimated fair value of warrants granted during the years ended April 30, 2024, were calculated using the Black-Scholes option-pricing model using the following assumptions:

	For the year ended April 30, 2024
Expected term (in years)	5.50
Volatility	92.9 %

Risk-free interest rate	3.95 – 4.65 %
Dividend yield	0.0 %

Expected Term: The expected term represents the contractual life of the warrants granted.

Expected Volatility: The Company uses an average historical stock price volatility of comparable public companies within the biotechnology and pharmaceutical industry that were deemed to be representative of future stock price trends as the Company only has a limited trading history for its common stock. The Company will continue to apply this process until a sufficient amount of historical information regarding the volatility of its own stock price becomes available.

Risk-Free Interest Rate: The Company based the risk-free interest rate over the expected term of the warrants based on the constant maturity rate of U.S. Treasury securities with similar maturities as of the date of the grant.

Expected Dividend: The Company has not paid and does not anticipate paying any dividends in the near future. Therefore, the expected dividend yield was zero.

9. OTHER RELATED PARTY TRANSACTIONS

In November 2022, the Company entered into a marketing and brand development agreement with Ault Alliance, Inc. ("AULT"), effective August 1, 2022, whereby AULT provided various marketing services over twelve months valued at $1.4 million. The Company had the right to pay the fee in cash or shares of Common Stock with a value of $225.00 per share. On November 11, 2022, the Company elected to pay the fee with 6,222 shares of Common Stock. The Company recorded the value of the agreement using the closing price of the Common Stock on November 11, 2022, and amortizes the expense over twelve months beginning in August 2022. At April 30, 2024, the balance of related party prepaid expenses was zero.

10. COMMITMENTS AND CONTINGENCIES

Contractual Obligations

On July 2, 2018, the Company entered into two Standard Exclusive License Agreements with Sublicensing Terms for AL001 with the Licensor and its affiliate, the University of South Florida (the "AL001 Licenses"), pursuant to which the Licensor granted the Company a royalty bearing exclusive worldwide licenses limited to the field of Alzheimer's, under United States Patent Nos. (i) 9,840,521, entitled "Organic Anion Lithium Ionic Cocrystal Compounds and Compositions", filed September 24, 2015 and granted December 12, 2017, and (ii) 9,603,869, entitled "Lithium Co-Crystals for Treatment of Neuropsychiatric Disorders", filed May 21, 2016 and granted March 28, 2017. On February 1, 2019, the Company entered into the First Amendments to the AL001 Licenses, on March 30, 2021, the Company entered into the Second Amendments to the AL001 Licenses and on June 8, 2023, the Company entered into the Third Amendments to the AL001 Licenses (collectively, the "AL001 License Agreements"). The Third Amendments to the AL001 Licenses modified the timing of the payments for the license fees.

The AL001 License Agreements require that the Company pay combined royalty payments of 4.5 % on net sales of products developed from the licensed technology for AL001. The Company has already paid an initial license fee of $ 200,000 for AL001. As an additional licensing fee for the license of the AL001 technologies, the Licensor received 14,853 shares of Common Stock. Minimum royalties for AL001 License Agreements are $ 40,000 on the first anniversary of the first commercial sale, $ 80,000 on the second anniversary of the first commercial sale and $ 100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the AL001 License Agreements.

On May 1, 2016, the Company entered into a Standard Exclusive License Agreement with Sublicensing Terms for ALZN002 with the Licensor (the "ALZN002 License"), pursuant to which the Licensor granted the Company a royalty bearing exclusive worldwide license limited to the field of Alzheimer's Immunotherapy and Diagnostics, under United States Patent No. 8,188,046, entitled "Amyloid Beta Peptides and Methods of Use", filed April 7, 2009 and granted May 29, 2012. On August 18, 2017, the Company entered into the First Amendment to the ALZN002 License, on May 7, 2018, the Company entered into the Second Amendment to the ALZN002 License, on January 31, 2019, the Company entered into the Third Amendment to the ALZN002 License, on January 24, 2020, the Company entered into the Fourth Amendment to the ALZN002 License, on March 30, 2021, the Company entered into the Fifth Amendment to the ALZN002 License, on April 17, 2023, the Company entered into the Sixth Amendment to the ALZN002 License and on December 11, 2023, the Company entered into the Seventh Amendment to the ALZN002 License (collectively, the "ALZN002 License Agreement"). The Seventh Amendment to the ALZN002 License modified the timing of the payments for the license fees.

The ALZN002 License Agreement requires the Company to pay royalty payments of 4 % on net sales of products developed from the licensed technology for ALZN002. The Company has already paid an initial license fee of $ 200,000 for ALZN002. As an additional licensing fee for the license of ALZN002, the Licensor received 24,012 shares of Common Stock. Minimum royalties for ALZN002 are $ 20,000 on the first anniversary of the first commercial sale, $ 40,000 on the second anniversary of the first commercial sale and $ 50,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the ALZN002 License Agreement.

On November 19, 2019, the Company entered into two Standard Exclusive License Agreements with Sublicensing Terms for two additional indications of AL001 with the Licensor (the "November AL001 License"), pursuant to which the Licensor granted the Company a royalty bearing exclusive worldwide licenses limited to the fields of (i) neurodegenerative diseases excluding Alzheimer's and (ii) psychiatric diseases and disorders. On March 30, 2021, the Company entered into the First Amendments to the November AL001 License and on April 17, 2023, the Company entered into the Second Amendments to the November AL001 License (collectively, the "November AL001 License Agreements"). The Second Amendments to the November AL001 License modified the timing of the payments for the license fees.

The November AL001 License Agreements require the Company to pay royalty payments of 3 % on net sales of products developed from the licensed technology for AL001 in those fields. The Company paid an initial license fee of $ 20,000 for the additional indications. Minimum royalties for November AL001 License Agreements are $ 40,000 on the first anniversary of the first commercial sale, $ 80,000 on the second anniversary of the first commercial sale and $ 100,000 on the third anniversary of the first commercial sale and every year thereafter, for the life of the November AL001 License Agreements.

These license agreements have an indefinite term that continue until the later of the date no licensed patent under the applicable agreement remains a pending application or enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, or the date on which the Company's obligations to pay royalties expire under the applicable license agreement. Under the various license agreements, if the Company fails to meet a milestone by its specified date, Licensor may terminate the license agreement. The Licensor was also granted a preemptive right to acquire such shares or other equity securities that may be issued from time to time by the Company while the Licensor remains the owner of any equity securities of the Company.

Additionally, the Company is required to pay milestone payments on the due dates to the Licensor for the license of the AL001 technologies and for the ALZN002 technology, as follows:

Original AL001 Licenses:

Payment	Due Date	Event
$ 50,000*	Completed September 2019	Pre-IND meeting
$ 65,000*	Completed June 2021	IND application filing
$ 190,000*	Completed December 2021	Upon first dosing of patient in a clinical trial
$ 500,000*	Completed March 2022	Upon completion of first clinical trial
$ 1,250,000	March 2025	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	8 years from the effective date of the agreement	Upon FDA approval

* Milestone met and completed

ALZN002 License:

Payment	Due Date
$ 50,000 *	Completed January 2022
$ 50,000	Upon first dosing of patient in first Phase I clinical trial
$ 500,000	Upon completion of first Phase IIB clinical trial
$ 1,000,000	Upon first patient treated in a Phase III clinical trial
$ 10,000,000	Upon first commercial sale

* Milestone met and completed

Additional AL001 Licenses:

Payment	Due Date	Event
$ 2,000,000	March 2026	Upon first patient treated in a Phase III clinical trial
$ 16,000,000	August 1, 2029	First commercial sale

11. EQUITY TRANSACTIONS

The Company is authorized to issue 10,000,000 shares of Preferred Stock, $ 0.0001 par value. The Board has designated 6,000 shares as Series B Convertible Preferred Stock. The rights, preferences, privileges and restrictions on the remaining authorized 9,994,000 shares of Preferred Stock have not been determined. The Board is authorized to create a new series of preferred shares and determine the number of shares, as well as the rights, preferences, privileges and restrictions granted to or imposed upon any series of preferred shares.

Series B Convertible Preferred Stock

On January 31, 2024, the Company and Ault Lending entered into the AL SPA for the purchase of up to 6,000 shares of Series B Convertible Preferred Stock and warrants to purchase shares up to 600,000 shares of Common Stock. The AL SPA provides that Ault Lending may purchase up to $ 6 million of Series B Convertible Preferred Stock in one or more closings. Ault Lending has the right to purchase up to $2 million of Series B Convertible Preferred Stock, on or before March 31, 2024, and the right to purchase up to $4 million of Series B Convertible Preferred Stock after March 31, 2024, but on or before March 31, 2025 (the “Termination Date”). The Agreement will automatically terminate if the final closing has not occurred prior to the Termination Date.

On January 31, 2024, the Company sold 1,220 shares of Series B Convertible Preferred Stock and warrants to purchase 122,000 shares of Common Stock with an exercise price of $ 12.00 , for a total purchase price of $ 1.22 million. The purchase price was paid by the cancellation of $ 1.15 million of cash advances made by Ault Lending to the Company between November 9, 2023 and January 31, 2024 and a subscription receivable of $ 70,000 .

On March 26, 2024, the Company sold 780 shares of Series B Convertible Preferred Stock and warrants to purchase 78,000 shares of Common Stock with an exercise price of $ 12.00 , for a total purchase price of $ 780,000 .

On April 29, 2024, the Company sold 100 shares of Series B Convertible Preferred Stock and warrants to purchase 10,000 shares of Common Stock with an exercise price of $ 12.00 , for a total purchase price of $ 100,000 .

The Series B Convertible Preferred Stock has a stated value of $1,000 per share (“Stated Value”) and does not accrue dividends. Each share of Series B Convertible Preferred Stock is convertible into a number of shares of Common Stock determined by dividing the Stated Value by $10.00 (the “Conversion Price”). The Conversion Price is subject to adjustment in the event of an issuance of Common Stock at a price per share lower than the Conversion Price then in effect, as well as upon customary stock splits, stock dividends, combinations or similar events. The holders of the Series B Convertible Preferred Stock are entitled to vote with the Common Stock as a single class on an as-converted basis, subject to applicable law provisions of the Delaware General Company Law and Nasdaq, provided however, that for purposes of complying with Nasdaq regulations, the conversion price, for purposes of determining the number of votes the holder of Series B Convertible Preferred Stock is entitled to cast, shall not be lower than $8.73 (the “Voting Floor Price”), which represents the closing sale price of the Common Stock on the trading day immediately prior to the Execution Date. The Voting Floor Price shall be adjusted for stock dividends, stock splits, stock combinations and other similar transactions. Upon a liquidation event the holders of Series B Convertible Preferred Stock receive a liquidation preference ahead of Common Stockholders.

The warrants have an exercise price of $12.00 (the “Exercise Price”) and become exercisable on the first business day after the six-month anniversary of issuance (the “Initial Exercise Date”) and have a five-year term, expiring on the fifth anniversary of the Initial Exercise Date. The Exercise Price is subject to adjustment in the event of an issuance of Common Stock at a price per share lower than the Exercise Price then in effect, as well as upon customary stock splits, stock dividends, combinations or similar events.

For the period ended January 31, 2024, the Company recorded the Series B Convertible Preferred Stock as mezzanine equity and the warrant as a liability. On March 21, 2024, the Company amended its Amended and Restated Certificate of Designations for the Series B Convertible Preferred Stock to remove certain change of control language. As a result, the Company reassessed the classification of both the Series B Convertible Preferred Stock and warrant and reclassified both the Series B Convertible Preferred Stock and warrant as permanent equity for the period ended April 30, 2024.

Common Stock

ALSF Investment

On April 30, 2019, the Company and ALSF entered into a securities purchase agreement (the "SPA") for the purchase of 66,667 shares of Common Stock for a total purchase price of $ 15,000,000 , or $ 225.00 per share with 33,333 warrants with a 5 -year life and an exercise price of $ 450.00 per share and vesting upon issuance. The total purchase price of $ 15,000,000 was in the form of a non-interest bearing note receivable with a 12 -month term from ALSF, a related party. The note was secured by a pledge of the purchased shares. Pursuant to the SPA, ALSF was entitled to full ratchet anti-dilution protection, most-favored nation status, denying the Company the right to enter into a variable rate transaction absent its consent, a right to participate in any future financing the Company may consummate and to have all the shares of Common Stock to which it is entitled under the SPA registered under the Securities Act within 180 days of the final closing of the IPO. In May 2021, the term of the note receivable was extended to December 31, 2023. On January 19, 2024, the Company and ALSF entered into a settlement agreement and release of claims whereby ALSF returned to the Company 66,117 shares of Common Stock and the ALSF Warrants for settlement of the outstanding balance of the note receivable in the amount of $ 14,876,293 .

At-the-Market Offering

On September 8, 2023, the Company entered into an At-the-Market Issuance Sales Agreement with Ascendiant Capital Markets, LLC, as sales agent to sell shares of its Common stock, having an aggregate offering price of up to approximately $9.8 million (the "Shares") from time to time, through the ATM Offering. On September 8, 2023, the Company filed a prospectus supplement with the SEC relating to the offer and sale of up to approximately $9.8 million in shares of Common Stock in the ATM Offering.

The offer and sale of the Shares was made pursuant to the Company's effective "shelf" registration statement on Form S-3 and an accompanying base prospectus contained therein (Registration Statement No. 333-273610) filed with the SEC on August 2, 2023 and declared effective by the SEC on August 10, 2023.

During the year ended April 30, 2024, the Company sold an aggregate of 107,682 shares of Common Stock pursuant to the ATM Offering for proceeds of $ 1.3 million.

The Company terminated its ATM Offering on May 6, 2024.

12. SUBSEQUENT EVENTS

On May 8, 2024, the Company and Orchid entered into the Orchid SPA for the purchase of up to 2,500 shares of Series A Convertible Preferred Stock and warrants to purchase shares up to 2,500,000 shares of Common Stock in several tranche closings.

On May 10, 2024, the Company sold 100 shares of Series A Convertible Preferred Stock and warrants to purchase 80,000 shares of Common Stock with an exercise price of $ 12.50 , for a total purchase price of $ 1.0 million. The purchase price was paid by the surrender and cancellation of a term note issued by the Company to Orchid of $ 311,356 , consisting of $ 310,000 of principal and $ 1,356 of accrued and unpaid interest, $ 100,000 discount and net cash of $ 588,644 .

On June 25, 2024, the Company sold 150 shares of Series A Convertible Preferred Stock and warrants to purchase 120,000 shares of Common Stock with an exercise price of $ 12.50 , for a total purchase price of $ 1.5 million. The purchase price was paid in cash.

Exhibit 4.4

DESCRIPTION OF CAPITAL STOCK

The following is a summary of all material characteristics of our capital stock as set forth in our certificate of incorporation and bylaws. The summary does not purport to be complete and is qualified in its entirety by reference to our certificate of incorporation and bylaws, and to the provisions of the General Corporation Law of the State of Delaware, as amended.

We are authorized to issue 300,000,000 shares of common stock, par value $0.0001 per share. As of July 29, 2024, there were 841,240 shares of our common stock issued and outstanding. The outstanding shares of our common stock are validly issued, fully paid and nonassessable.

We are authorized to issue up to 10,000,000 shares of preferred stock, par value $0.0001 per share. Of these shares of preferred stock, 3,000 shares are designated as Series A convertible preferred stock and 6,000 shares are designated as Series B convertible preferred stock. As of July 29, 2024, there were approximately 192.9884 shares of Series A convertible preferred stock outstanding and 2,100 shares of Series B convertible preferred stock outstanding.

Common Stock

Holders of our shares of common stock are entitled to one vote for each share on all matters submitted to a stockholder vote. Holders of our common stock do not have cumulative voting rights. Therefore, holders of a majority of the shares of our common stock voting for the election of directors can elect all of the directors. Holders of our common stock representing a majority of the voting power of our capital stock issued, outstanding and entitled to vote, represented in person or by proxy, are necessary to constitute a quorum at any meeting of stockholders. A vote by the holders of a majority of our outstanding shares is required to effectuate certain fundamental corporate changes such as liquidation, merger or certain amendments to our certificate of incorporation.

Holders of our common stock are entitled to share in all dividends that our Board of Directors, in its discretion, declares from legally available funds. In the event of a liquidation, dissolution or winding up, each outstanding share entitles its holder to participate pro rata in all assets that remain after payment of liabilities and after providing for each class of stock, if any, having preference over our common stock. Our common stock has no preemptive, subscription or conversion rights and there are no redemption provisions applicable to our common stock.

Preferred Stock

The shares of preferred stock may be issued in series, and shall have such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, as shall be stated and expressed in the resolution or resolutions providing for the issuance of such stock adopted from time to time by the board of directors. The board of directors is expressly vested with the authority to determine and fix in the resolution or resolutions providing for the issuances of preferred stock the voting powers, designations, preferences and rights, and the qualifications, limitations or restrictions thereof, of each such series to the full extent now or hereafter permitted by the laws of the State of Delaware.

The authorized shares of preferred stock will be available for issuance without further action by our stockholders unless such action is required by applicable law or the rules of any stock exchange or automated quotation system on which our securities may be listed or traded. The Nasdaq Stock Market currently requires stockholder approval as a prerequisite to listing shares in several circumstances, including, in certain circumstances, where the issuance of shares could result in an increase in the number of shares of common stock outstanding, or in the amount of voting securities outstanding, of at least 20%.

Transfer Agent and Registrar

The Transfer Agent and Registrar for our common stock is Computershare, 8742 Lucent Blvd., Suite 225, Highlands Ranch, CO 80129.

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statements on Form S-8 (File No. 333-257873) and on Form S-3 (File No. 333-273610) of Alzamend Neuro, Inc. (the "Company") of our report dated July 30, 2024, relating to the financial statements as of April 30, 2024 and for the year then ended, which includes an explanatory paragraph relating to the uncertainty of the Company's ability to continue as a going concern, which appear in the Company's Annual Report on Form 10-K for the fiscal year ended April 30, 2024.

HASKELL & WHITE LLP

Irvine, California
July 30, 2024

Exhibit 23.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement (No. 333-257873) on Form S-8 and Registration Statement (No. 333-273610) on Form S-3 of Alzamend Neuro, Inc. (the Company) of our report, which expresses an unqualified opinion and includes an explanatory paragraph relating to the conditions and events that raise substantial doubt regarding the Company's ability to continue as a going concern, relating to the financial statements of Alzamend Neuro, Inc., appearing in this Annual Report on Form 10-K for the year ended April 30, 2023.

/s/ BAKER TILLY US, LLP

San Diego, CA
July 30, 2024

EXHIBIT 31.1

Certification of the Chief Executive Officer
Pursuant to §240.13a- 14 or §240. 15d- 14 of the Securities Exchange Act of 1934, as amended

I, Stephan Jackman, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended April 30, 2024 of Alzamend Neuro, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal controls over financial reporting, or caused such internal controls over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: July 30, 2024

By: /s/ Stephan Jackman
Name: Stephan Jackman
Title: Chief Executive Officer
(Principal Executive Officer)

EXHIBIT 31.2

Certification of the Chief Financial Officer
Pursuant to §240.13a- 14 or §240. 15d- 14 of the Securities Exchange Act of 1934, as amended

I, David J. Katzoff, certify that:

1. I have reviewed this Annual Report on Form 10-K for the year ended April 30, 2024 of Alzamend Neuro, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and we have:

a) designed such disclosure controls and procedures or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) designed such internal controls over financial reporting, or caused such internal controls over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of registrant's board of directors (or persons performing the equivalent function):

a) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: July 30, 2024

By: /s/ David J. Katzoff
Name: David J. Katzoff
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Alzamend Neuro, Inc. (the "Registrant") on Form 10-K for the period ended April 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Stephan Jackman, Principal Executive Officer, and I, David J. Katzoff, Principal Financial Officer and Principal Accounting Officer of the Registrant, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

(1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Registrant.

Date: July 30, 2024

By: /s/ Stephan Jackman
Name: Stephan Jackman
Title: Chief Executive Officer
(Principal Executive Officer)

Date: July 30, 2024

By: /s/ David J. Katzoff
Name: David J. Katzoff
Title: Chief Financial Officer
(Principal Financial and Accounting Officer)

This certification accompanies the Annual Report on Form 10-K to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Alzamend Neuro, Inc. under the Securities Act of 1933, as amended, or the Exchange Act (whether made before or after the date of the Form 10-K), irrespective of any general incorporation language contained in such filing.

Exhibit 97.1

ALZAMEND NEURO, INC.
DODD-FRANK CLAWBACK POLICY

The Board of Directors (the "**Board**") of Alzamend Neuro, Inc. (the "**Company**") has adopted this clawback policy (the "**Policy**") as a supplement to any other clawback policies in effect now or in the future at the Company to provide for the recovery of erroneously awarded Incentive-Based Compensation from Executive Officers. This Policy shall be interpreted to comply with the clawback rules found in 17 C.F.R. §240.10D and Listing Rule 5608(c) of the Nasdaq Stock Market (the "**Exchange**"), and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

1. Definitions. 17 C.F.R. §240.10D-1(d) defines the terms "**Executive Officer**," "**Financial Reporting Measures**," "**Incentive-Based Compensation**," and "**Received**." As used herein, these terms shall have the same meaning as in that regulation.

2. Application of the Policy. This Policy shall only apply in the event that the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period. In the event of such an accounting restatement, the Company will recover reasonably promptly the Erroneously Awarded Compensation Received in accordance with this Policy.

3. Recovery Period. The Incentive-Based Compensation subject to clawback is the Incentive-Based Compensation Received by an Executive Officer (1) after beginning service as an Executive Officer and (2) during the three completed fiscal years immediately preceding the date that the Company is required to prepare an accounting restatement as described in section 2, provided that the person served as an Executive Officer at any time during the performance period applicable to the Incentive-Based Compensation in question (whether or not such person is serving as an Executive Officer at the time the Erroneously Awarded Compensation is required to be repaid to the Company). The date that the Company is required to prepare an accounting restatement shall be determined pursuant to 17 C.F.R. §240.10D-1(b)(1)(ii).

(a) Notwithstanding the foregoing, the Policy shall only apply if the Incentive-Based Compensation is Received (1) while the Company has a class of securities listed on the Exchange and (2) on or after October 2, 2023.

(b) See 17 C.F.R. §240.10D-1(b)(1)(i) for certain circumstances under which the Policy will apply to Incentive-Based Compensation Received during a transition period arising due to a change in the Company's fiscal year.

4. Erroneously Awarded Compensation. The amount of Incentive-Based Compensation subject to recovery under this Policy with respect to each Executive Officer in connection with an accounting restatement described in Section 2 ("**Erroneously Awarded Compensation**") is the amount of Incentive-Based Compensation Received that exceeds the amount of Incentive Based-Compensation that otherwise would have been Received had it been determined based on the restated amounts and shall be computed without regard to any taxes paid. For Incentive-Based Compensation based on the Company's stock price or total shareholder return, where the amount of Erroneously Awarded Compensation is not subject to mathematical recalculation directly from the information in an accounting restatement: (1) the amount shall be based on a reasonable estimate of the effect of the accounting restatement on the Company's stock price or total shareholder return upon which the Incentive-Based Compensation was Received; and (2) the Company must maintain documentation of the determination of that reasonable estimate and provide such documentation to the Exchange.

5. Recovery of Erroneously Awarded Compensation. The Company shall recover reasonably promptly any Erroneously Awarded Compensation except to the extent that the conditions of paragraphs (a), (b), or (c) below apply. The Board shall determine the amount of Erroneously Awarded Compensation Received by each Executive Officer, shall promptly notify each Executive Officer of such amount and demand repayment or return of such compensation based on a repayment schedule determined by the Board in a manner that complies with this "reasonably promptly" requirement. Such determination shall be consistent with any applicable legal guidance, by the Securities and Exchange Commission (the "**SEC**"), judicial opinion, or otherwise. The determination of "reasonably promptly" may vary from case to case and the Board is authorized to adopt additional rules to further describe what repayment schedules satisfy this requirement.

(a) Erroneously Awarded Compensation need not be recovered if the direct expense paid to a third party to assist in enforcing the Policy would exceed the amount to be recovered and the Board has made a determination that recovery would be impracticable. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on expense of enforcement, the Company shall make a reasonable attempt to recover such Erroneously Awarded Compensation, document such reasonable attempt(s) to recover, and provide that documentation to the Exchange.

(b) Erroneously Awarded Compensation need not be recovered if recovery would violate home country law where that law was adopted prior to November 28, 2022. Before concluding that it would be impracticable to recover any amount of Erroneously Awarded Compensation based on violation of home country law, the Company shall obtain an opinion of home country counsel, acceptable to the Exchange, that recovery would result in such a violation and shall provide such opinion to the Exchange.

(c) Erroneously Awarded Compensation need not be recovered if recovery would likely cause an otherwise tax-qualified retirement plan, under which benefits are broadly available to employees of the Company, to fail to meet the requirements of 26 U.S.C. 401(a)(13) or 26 U.S.C. 411(a) and regulations thereunder.

6. Board Decisions. Decisions of the Board with respect to this Policy shall be final, conclusive and binding on all Executive Officers subject to this Policy, unless determined to be an abuse of discretion.

7. No Indemnification. Notwithstanding anything to the contrary in any other policy of the Company or any agreement between the Company and an Executive Officer, no Executive Officer shall be indemnified by the Company against the loss of any Erroneously Awarded Compensation or any claims related to the Company's enforcement of its rights under this Policy.

8. Agreement to Policy by Executive Officers. The Board shall take reasonable steps to inform Executive Officers of this Policy and obtain their agreement

to this Policy, which steps may constitute the inclusion of this Policy as an attachment to any award that is accepted by the Executive Officer.

9. Other Recovery Rights. Any employment agreement, equity award agreement, compensatory plan or any other agreement or arrangement with an Executive Officer shall be deemed to include, as a condition to the grant of any benefit thereunder, an agreement by the Executive Officer to abide by the terms of this Policy. Any right of recovery under this Policy is in addition to, and not in lieu of, any other remedies or rights of recovery that may be available to the Company under applicable law, regulation or rule or pursuant to the terms of any policy of the Company or any provision in any employment agreement, equity award agreement, compensatory plan, agreement or other arrangement. Without limiting the generality of the foregoing, (i) with respect to Executive Officers, if application of the provisions of any section of the Company's stock incentive plans, either currently in place or adopted in the future (the "**Plan Clawback Provisions**") to any Executive Officer provides that a greater amount of such compensation may be subject to clawback, the Board may, in its sole discretion, elect to apply the Plan Clawback Provisions; and (ii) with respect to other persons employed by or providing services to the Company, this Policy does not limit or supersede the provisions of any section of the Company's stock incentive plans, either currently in place or adopted in the future, and the Board may elect to apply the Plan Clawback Provisions in the Board's sole discretion.

10. Disclosure. The Company shall file all disclosures with respect to this Policy required by applicable SEC filings and rules.

11. Amendments. The Board may amend this Policy from time to time in its discretion and shall amend this Policy as it deems necessary. Notwithstanding anything in this Section 11 to the contrary, no amendment or termination of this Policy shall be effective if such amendment or termination would (after taking into account any actions taken by the Company contemporaneously with such amendment or termination) cause the Company to violate any federal securities laws, SEC rule or Exchange rule.

[end of policy]

EXHIBIT A

ALZAMEND NEURO, INC. DODD-FRANK CLAWBACK POLICY

ACKNOWLEDGMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Alzamend Neuro, Inc. (the "**Company**") Dodd-Frank Clawback Policy (the "**Policy**").

By signing this Acknowledgment Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Erroneously Awarded Compensation (as defined in the Policy) to the Company to the extent required by, and in a manner consistent with, the Policy.

Signature

Print Name

Date