August 26, 2024

Alzamend Neuro Issues Letter to Stockholders

- ***Alzamend recently announced partnership with Massachusetts General Hospital for five phase II clinical trials of AL001, involving healthy human subjects and patients with Alzheimer's, BD, MDD and PTSD***
- ***Alzamend has executed an agreement to provide sufficient capital over the next 18 months to finance the initiation and progression of AL001 and ALZN002 clinical trials***

ATLANTA--(BUSINESS WIRE)-- Alzamend Neuro, Inc. (Nasdaq: ALZN) ("**Alzamend**"), 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**"), today shared a letter from its Chief Executive Officer, Stephan Jackman.

Dear Stockholders,

I am reaching out to share an update about our clinical programs and the outlook for the future.

Planned Clinical Trials

The heart of Alzamend's mission lies in pioneering breakthroughs that have the potential to transform lives. I am thrilled to share that our planned clinical trials are currently on pace to make significant progress over the next year. The dedication of our research and development partners, in collaboration with experts in the field, has propelled us closer to potentially achieving significant milestones.

AL001

Our lead therapeutic drug candidate, AL001, is a novel lithium-delivery system that has the potential to deliver benefits of marketed lithium salts while mitigating or avoiding currently experienced toxicities associated with lithium. Our preclinical data for AL001 treatment showed prevention of cognitive deficits, depression and irritability in mice models, and has shown to be superior in improving associative learning, memory, and irritability, compared with lithium carbonate treatments. In March 2022, we announced that full data sets from our Phase I bioequivalent study affirmed that the extent of lithium absorption in plasma indicated that AL001 at 150 mg dosage is bioequivalent to the marketed 300 mg lithium carbonate product. In June 2023, we announced topline data from our Phase IIA multiple-ascending dose study in Alzheimer's and healthy patients, which initiated in May 2022. Results from the Phase IIA study identified a maximum tolerated dose ("**MTD**"), as assessed by an independent safety review committee. This MTD, providing lithium at a lithium carbonate equivalent dose of 240 mg 3-times daily ("**TID**"), is designed to be unlikely to require therapeutic drug monitoring ("**TDM**"). Moreover, this dose is designed to distribute more

lithium to the brain but at lower systemic exposure, resulting in an improved safety profile compared to currently marketed lithium salts and thereby avoiding clinical disadvantages.

In the latter half of 2023, Alzamend submitted and received "Study May Proceed" letters from the United States Food and Drug Administration ("**FDA**") encompassing three additional investigational new drug ("**IND**") applications for AL001 in BD, MDD, and PTSD. Alzamend recently announced it reached a partnership agreement with Massachusetts General Hospital to serve as its contract research organization ("**CRO**") in connection with five Phase II clinical trials, one for healthy human subjects, and one each in patients with Alzheimer's, BD, MDD and PTSD. The clinical trials will be designed to determine relative increased lithium levels in the brain of AL001 compared to a marketed lithium salt.

One of Alzamend's goals 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. Lithium is a commonly prescribed drug for manic episodes in BD type 1 as well as maintenance therapy of BD in patients with a history of a manic episode. Lithium was the first mood stabilizer approved by the FDA and is still a first-line treatment option (considered the "gold standard") and is utilized off-label for MDD and PTSD. Alzamend believes these programs may qualify for the 505(b)(2) pathway for FDA approval, which is available to new formulations of an approved drug. Alzamend anticipates initiating all five of these studies in the first half of 2025, with exact dates to be announced before the end of 2024.

ALZN002

Our secondary therapeutic drug candidate, ALZN002, is a proprietary "active" immunotherapy product, which means it is produced by each patient's immune system.

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. 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 goal of this treatment approach 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.

In April 2023, we announced the initiation of a Phase I/IIA clinical trial for ALZN002. The purpose of this trial is to assess the safety, tolerability, and efficacy of multiple ascending doses of ALZN002 compared with that of placebo in 20-30 subjects with mild to moderate morbidity. In February 2024, we received notice from our CRO on the clinical trial that it was terminating our contract with them. We are currently pursuing the engagement of a replacement CRO and anticipate that the study will resume in the fourth quarter of 2024.

Financial Condition

In an ever-evolving industry, financial prudence remains a cornerstone of our strategic approach. Our disciplined cost management, prudent resource allocation, and strategic investments in high-potential areas have collectively contributed to our financial resilience.

We believe that this approach not only fortifies our foundation but also preserves our ability to achieve growth in the years ahead.

We raised capital through an at-the-market sales agreement in the fourth quarter of 2023 through the first quarter of 2024, which we strategically utilized from time to time with a goal of not disrupting the market. We also entered into two separate securities purchase agreements in 2024. The first one with an entity associated with our founder and largest stockholder, pursuant to which we have received $2.1 million in gross proceeds to date, and which the investor has the right to purchase up to an additional $3.9 million of securities through March 31, 2025. The second agreement with an outside investor, pursuant to which we have received $7.0 million in gross proceeds to date. Under the second agreement, the investor is obligated to purchase, subject to certain conditions, up to an additional $18.0 million of securities through January 2026. Please see our Securities and Exchange Commission filings for additional information regarding the securities purchase agreements described above and the terms of such financing transactions.

We remain grateful for the support from our investors as we continue to apply those strategic investments to drive our anticipated future growth. Our strategic roadmap includes further optimizing operational efficiencies, expanding our footprint within the industry, and deepening our commitment to bringing our therapeutics to the market. As we progress through 2024 and into 2025, we look forward to sharing with you updates on our clinical progress.

Nasdaq Compliance

In April 2024, we announced that a Nasdaq Hearings Panel granted Alzamend's request to continue its listing on The Nasdaq Capital Market ("**Nasdaq**"), subject to Alzamend demonstrating compliance, on or before September 23, 2024, with Listing Rule 5550(b)(1), which requires stockholder equity of at least $2.5 million (the "**Stockholder Equity Rule**") and satisfying all applicable requirements for continued listing on Nasdaq. We believe that the capital raises from the securities purchase agreements described above will enable us to achieve compliance with the Stockholder Equity Rule within the timeframe required by Nasdaq.

I want to express my sincere gratitude for your continued trust and support. I fully understand that the market has not been kind these past few years. Our stockholders play a pivotal role in our journey, and we remain dedicated to delivering long-term value through prudent fiscal management and pioneering advancements in biotechnology.

We eagerly anticipate the opportunities that lie ahead and are confident in our ability to create lasting value for all stockholders.

Sincerely,

Stephan Jackman
Chief Executive Officer, Alzamend Neuro

About Alzamend Neuro

Alzamend Neuro is a clinical-stage biopharmaceutical company focused on developing novel

products for the treatment of Alzheimer's, BD, MDD and PTSD. Our mission is to rapidly develop and market safe and effective treatments. Our current pipeline consists of two novel therapeutic drug candidates, AL001 - a patented ionic cocrystal technology delivering lithium via a therapeutic combination of lithium, salicylate and L-proline, 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. Both of our product candidates are licensed from the University of South Florida Research Foundation, Inc. pursuant to royalty-bearing exclusive worldwide licenses.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. These forward-looking statements generally include statements that are predictive in nature and depend upon or refer to future events or conditions, and include words such as "believes," "plans," "anticipates," "projects," "estimates," "expects," "intends," "strategy," "future," "opportunity," "may," "will," "should," "could," "potential," or similar expressions. Statements that are not historical facts are forward-looking statements. Forward-looking statements are based on current beliefs and assumptions that are subject to risks and uncertainties. Forward-looking statements speak only as of the date they are made, and Alzamend undertakes no obligation to update any of them publicly in light of new information or future events. Actual results could differ materially from those contained in any forward-looking statement as a result of various factors. More information, including potential risk factors, that could affect Alzamend's business and financial results are included in Alzamend's filings with the U.S. Securities and Exchange Commission. All filings are available at www.sec.gov and on Alzamend's website at www.Alzamend.com.

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