UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 31, 2022

ALZAMEND NEURO, INC.

(Exact name of registrant as specified in its charter)

Delaware	001-40483	81-1822909
(State or other jurisdiction of incorporation or organization)	(Commission File Number)	(I.R.S. Employer Identification No.)

3500 Lenox Rd. NE, Suite 1500, Atlanta, GA 30326
(Address of principal executive offices) (Zip Code)

(844) 722-6333
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	ALZN	The Nasdaq Capital Market

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

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. ☐

Item 7.01 Regulation FD Disclosure

On October 31, 2022, Alzamend Neuro, Inc. (the "**Company**") issued a press release to announce that it had received a "Study May Proceed" letter from the U.S. Food and Drug Administration for a phase I/IIA clinical trial under its Investigational New Drug application for an immunotherapy (ALZN002) to treat mild to moderate dementia of the Alzheimer's type. The Company expects that the first patient in this trial will be dosed in the first quarter of 2023. A copy of the press release is furnished herewith as **Exhibit 99.1** and is incorporated by reference herein.

In accordance with General Instruction B.2 of Form 8-K, the information under this item shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall such information be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing. This report will not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

The Securities and Exchange Commission encourages registrants to disclose forward-looking information so that investors can better understand the future prospects of a registrant and make informed investment decisions. This Current Report on Form 8-K and exhibits may contain these types of statements, which are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, and which involve risks, uncertainties and reflect the Registrant's judgment as of the date of this Current Report on Form 8-K. Forward-looking statements may relate to, among other things, operating results and are indicated by words or phrases such as "expects," "should," "will," and similar words or phrases. These statements are subject to inherent uncertainties and risks that could cause actual results to differ materially from those anticipated at the date of this Current Report on Form 8-K. Investors are cautioned not to rely unduly on forward-looking statements when evaluating the information presented within.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press release issued by the Company on October 31, 2022.
101	Pursuant to Rule 406 of Regulation S-T, the cover page is formatted in Inline XBRL (Inline eXtensible Business Reporting Language).
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101).

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ALZAMEND NEURO, INC.

Dated: October 31, 2022

/s/ Henry Nisser
Henry Nisser
Executive Vice President and General Counsel

Alzamend Neuro Receives FDA "Study May Proceed" Letter for Phase I/IIA Trial Under Its Investigational New Drug Application for an Immunotherapy Vaccine (ALZN002) to Treat Mild to Moderate Dementia of the Alzheimer's Type

ATLANTA, GA, October 31, 2022 -- Alzamend Neuro, Inc. (Nasdaq: ALZN) ("Alzamend"), an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer's disease ("Alzheimer's"), bipolar disorder, major depressive disorder ("MDD") and post-traumatic stress disorder ("PTSD"), today announced receipt of a "Study May Proceed" letter from the U.S. Food and Drug Administration ("FDA") for a phase I/IIA clinical trial under its Investigational New Drug ("IND") application for an immunotherapy (ALZN002) to treat mild to moderate dementia of the Alzheimer's type.

"We are grateful to receive this timely, favorable response from the FDA to initiate a Phase I/IIA trial with ALZN002. There remains a need to develop new therapies that alter the progression of Alzheimer's and prevent, reverse or slow neurodegeneration and cognitive decline," said Stephan Jackman, Chief Executive Officer of Alzamend. "We strongly believe that the ALZN002 patient-specific immunotherapeutic vaccine has the potential to achieve these objectives and bring aid to the millions of Americans afflicted with this devastating disease. We are advancing the process and expect that the first patient will be dosed in the first quarter of 2023."

About ALZN002

ALZN002 is a proprietary "active" immunotherapy product, which means it is produced by each patient's immune system. It consists of autologous dendritic cells ("DCs"), which are activated white blood cells taken from each individual patient that are then 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 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.

The ALZN002 DC treatment is, by definition, an individual-patient-specific therapy since these autologous DCs are administered to the same patient from whom they were removed. Each patient will undergo leukapheresis, i.e., removal and return to the body of white blood cells. This procedure will isolate each patient's peripheral blood monocytes from the obtained white blood cells. These are subsequently differentiated outside the body into DCs that are engineered to induce immunogenicity (search and destroy capability) towards amyloid, the protein associated with Alzheimer's in the patient's body, but to be otherwise tolerated as natural to the body to avoid adverse side effects.

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 is expected to provide a safe and effective treatment for Alzheimer's sufferers that requires considerably less frequent treatment visits compared to passive immunity approaches.

The IND supports initial deployment of a Phase I/IIA clinical trial, ALZN002-01, a first-in-human, randomized, double-blind, placebo-controlled, parallel-group study. The purpose of this trial will be 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 dementia of the Alzheimer's type. Also, the trial will be designed to determine the optimal dosage of ALZN002 for treatment of patients with Alzheimer's in a larger Phase IIB efficacy and safety clinical trial (ALZN002-02), which Alzamend expects to initiate within three months of receiving data from the initial trial.

Multiple pre-clinical studies have been conducted using a transgenic (or genetically modified) mouse model of Alzheimer's disease at the University of South Florida and Charles River Laboratories that reported encouraging Alzheimer's disease-related measurements and neurobehavioral effects, supporting this IND application. Strong evidence of significant ALZN002-mediated amyloid plaque reductions was observed in mouse disease models. There were no undue adverse findings in a good laboratory practices toxicology study, which consisted of five injections administered over a 90-day period and evaluated for 90 days after the last dose. Histopathology results demonstrated that there were no indication of T-cell infiltration or meningoencephalitis (inflammation of the membranes that surround the brain), suggesting that ALZN002 is safe and tolerable. In addition, there were no treatment-related mortalities or reports of adverse effects on clinical observations during the main study or the recovery phase.

About Alzamend Neuro

Alzamend is an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer's, bipolar disorder, 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, proline and salicylate, 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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