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): September 30, 2021

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.)

3802 Spectrum Boulevard, Suite 112C, Tampa, FL 33612
(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 September 30, 2021, Alzamend Neuro, Inc. (the "**Company**") issued a press release to announce that the U.S. Food and Drug Administration has issued a written response to the Company's meeting request relating to its Type B Pre-Investigational New Drug application for the clinical development of AL002. A copy of the press release is furnished herewith as **Exhibit 99.1** and is incorporated by reference herein.

The information contained in this Current Report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the "**Securities Act**") or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The furnishing of the information in this Current Report on Form 8-K is not intended to, and does not, constitute a representation that such furnishing is required by Regulation FD or that the information contained in this Current Report on Form 8-K constitutes material investor information that is not otherwise publicly available.

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 Exhibits and Financial Statements.

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release issued on September 30, 2021
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: September 30, 2021

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

Alzamend Neuro Receives Positive Pre-IND Response From FDA for AL002, a Cell-Based Therapeutic Vaccine That Seeks to Restore the Ability of Patients' Immunological System to Combat Alzheimer's Disease

FDA Agrees to Alzamend's Plan to Conduct a Combined Phase 1 and 2 Clinical Trial for AL002

TAMPA, FL., September 30, 2021—Alzamend Neuro, Inc. (Nasdaq: ALZN) ("**Alzamend**"), an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, today announced that it has received a written response to its meeting request relating to its Type B Pre-Investigational New Drug ("**IND**") application from the U.S. Food and Drug Administration (the "**FDA**") providing a path for Alzamend's planned clinical development of AL002. AL002 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.

"We appreciate the thorough and meaningful response from the FDA, which provides us with the information and clarity needed to submit the IND application to initiate a clinical trial for AL002," said Stephan Jackman, Alzamend's Chief Executive Officer. "Preclinical work supports AL002 being associated with a positive anti-inflammatory response and a decrease in brain amyloid contents. Based on AL002's positive toxicology results, the biologic nature of this product and the urgent need to deliver treatments for Alzheimer's to patients, Alzamend proposed to, and the FDA agreed, conduct a combined Phase 1/2 study. We appreciate the FDA's recommendations, guidance and other helpful advice. We plan to augment our proposed clinical trial protocols and proceed accordingly."

Based on the FDA's written feedback, Alzamend anticipates filing the IND by the end of November 2021 and initiating the clinical trial of AL002 in the first quarter of 2022.

About AL002
AL002 is a patented method using a mutant-peptide sensitized cell as a cell-based therapeutic vaccine that reduces beta-amyloid plaque and seeks to restore the ability of the patient's immunological system to combat Alzheimer's disease. This therapy is intended to work by stimulating the body's own immune system to prevent the formation and breakdown of beta amyloids, which build up in the brain to form a plaque that subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's.

About Alzamend Neuro
We are early clinical stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's. 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 AL002 - 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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