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 5, 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:

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
o 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 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. o

Item 7.01 Regulation FD Disclosure

On October 5, 2022, Alzamend Neuro, Inc. (the "**Company**") issued a press release to announce that it has dosed its first healthy adult subject in its Phase IIA multiple ascending dose study of AL001 in subjects with dementia related to Alzheimer's Disease. This blinded, placebo-controlled trial (AL001-02) was initiated in May 2022 and is designed to evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions and determine the maximum tolerated dose. 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 5, 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 5, 2022

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

Exhibit 99.1

Alzamend Neuro Announces Addition of Healthy Subjects to Ongoing Phase IIA Clinical Trial for AL001 in Alzheimer's Subjects

Alzamend pursuing additional indications of bipolar disorder, major depressive disorder and post-traumatic stress disorder for AL001

ATLANTA, GA, October 5, 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 it has dosed its first healthy adult subject in its Phase IIA multiple ascending dose ("MAD") study of AL001 in subjects with dementia related to Alzheimer's. This blinded, placebo-controlled trial (AL001-02) was initiated in May 2022 and is designed to evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions and determine the maximum tolerated dose.

Alzamend is also pursuing AL001 for the treatment of bipolar disorder, MDD and PTSD. Based upon a recommendation by the U.S. Food and Drug Administration ("FDA") after its review and commentary on Alzamend's pre-investigational new drug ("IND") briefing package for development of AL001 for bipolar disorder, MDD and PTSD, the ongoing clinical trial in Alzheimer's patients has been expanded. As the safety and tolerability of AL001 would need to be tested in healthy and elderly adults before Alzamend could initiate later-stage testing of AL001 for bipolar disorder, MDD and PTSD, the addition of healthy and elderly adults to the on-going AL001-02 clinical trial would expedite the timing of further clinical trials. Alzamend will test AL001 in four healthy adult and elderly adult cohorts of eight subjects under MAD conditions.

AL001, a novel lithium-salicylate-L-proline engineered ionic cocrystal lithium delivery system, is under development as an oral treatment for patients with Alzheimer's disease, and more recently for other neurodegenerative and neuropsychiatric disorders. AL001 has the potential to deliver benefits of marketed lithium carbonate while mitigating or avoiding current toxicities associated with lithium. In a Phase I relative bioavailability comparison of AL001 to lithium carbonate completed in March 2022, AL001 was shown to be bioequivalent at 50% less the dosage of lithium carbonate and the shapes of the lithium plasma concentration versus time curves were similar. Additionally, AL001 salicylate plasma concentrations were observed to be well tolerated and consistently within safe limits and the safety profiles of both AL001 and the marketed lithium carbonate capsule were benign.

"Adding healthy adult and elderly subjects to the Phase IIA MAD clinical trial is in response to recent FDA guidance regarding our forthcoming INDs for AL001 as a treatment of bipolar disorder, MDD and PTSD," said Stephan Jackman, Chief Executive Officer of Alzamend. "We are one step closer to providing patients, caregivers and clinicians with a major improvement over current lithium-based treatments that can help over 40 million Americans suffering from Alzheimer's, bipolar disorder, MDD and PTSD. We look forward to completing the AL001-02 study and further advancing clinical development of this promising potential therapeutic."

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, 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.

Contacts:
Email: Info@Alzamend.com or call: 1-844-722-6333