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): March 22, 2023

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.)

3480 Peachtree Road NE, Second Floor, Suite 103, 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 March 22, 2023, Alzamend Neuro, Inc. (the "**Company**") issued a press release to announce that it had completed the clinical portion of its Phase IIA multiple ascending dose clinical trial for AL001 treatment of dementia related to Alzheimer's disease. The Company expects to report topline data in June 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 March 22, 2023.
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: March 22, 2023

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

Exhibit 99.1

Alzamend Neuro Announces Completion of Clinical Portion of Phase IIA Multiple Ascending Dose Clinical Trial for AL001 Treatment of Dementia Related to Alzheimer's

Topline data expected in June 2023

ATLANTA, GA, March 22, 2023 -- 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 the completion of the clinical portion of its Phase IIA multiple ascending dose ("**MAD**") study for dementia related to Alzheimer's. The MAD study's purpose was to evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions and determine the maximum tolerated dose in patients diagnosed with mild to moderate Alzheimer's and healthy subjects. AL001 is a novel lithium-delivery system; it is a lithium-salicylate-L-proline engineered ionic cocrystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's. AL001 has the potential to deliver benefits of marketed lithium carbonate while mitigating or avoiding current toxicities associated with lithium.

"We strongly believe that AL001's patented ionic cocrystal technology could potentially provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating over 40 million American suffering from Alzheimer's, bipolar disorder, MDD and PTSD", said Stephan Jackman, Chief Executive Officer of Alzamend. "We look forward to reporting topline data in June 2023 and further advancing clinical development of this promising potential therapeutic."

About AL001 Phase IIA Study

Having completed the clinical portion of the MAD study, the resulting pharmacokinetic and statistical data are undergoing evaluation of the safety and tolerability of AL001 under multiple-dose, steady-state conditions. This is to characterize the maximum tolerated dose in healthy young and elderly subjects and in subjects diagnosed with mild to moderate Alzheimer's. Potentially safe and effective doses will thereby be determined for deployment in planned subsequent Phase IIA clinical trials involving Alzheimer's, bipolar disorder, MDD and PTSD subjects. Lithium has been well characterized for safety and is approved/marketed in multiple formulations for bipolar affective disorders. AL001 lithium ascending dosing for the MAD cohorts tested incremental fractions of the usual lithium exposure for treatment of bipolar affective disorder, with the target lithium dose for Alzheimer's treatment expected at a level that will not require therapeutic drug monitoring. In each of the multiple healthy young/elderly and Alzheimer's cohorts, consisting of 6 active and 2 placebo patients each (as per randomization), multiple ascending doses were administered three times daily for 14 days under fasted conditions up to tolerability/safety limits that included the highest dose permitted per protocol.

About Alzamend Neuro

Alzamend is an 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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