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): June 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 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. ¨

Item 7.01 Regulation FD Disclosure

On June 22, 2023, Alzamend Neuro, Inc. (the "**Company**") issued a press release to announce positive topline data results from its completed Phase IIA multiple ascending dose clinical trial for AL001 treatment of dementia related to Alzheimer's disease. 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 June 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: June 22, 2023

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

Alzamend Neuro Announces Positive Phase IIA Clinical Trial Results for AL001

- ***Topline data identifies maximum tolerated dose from Phase IIA multiple ascending dose study as assessed by an independent safety review committee***
- ***Identified dose is unlikely to require lithium therapeutic drug monitoring***
- ***Alzamend plans two Phase II clinical trials to investigate the safety and efficacy of AL001 for patients with mild to moderate Alzheimer's disease***
- ***Investigational new drug applications to be filed for AL001 for treatment of bipolar disorder, major depressive disorder and post-traumatic stress disorder***

ATLANTA, GA, June 22, 2023 -- 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 ("**BPD**"), major depressive disorder ("**MDD**") and post-traumatic stress disorder ("**PTSD**"), today announced that it has successfully identified a maximum tolerated dose ('**MTD**") for development of AL001 from a multiple-ascending dose study as assessed by an independent safety review committee. This dose, providing lithium at a lithium carbonate equivalent dose of 240 mg 3-times daily ("**TID**"), is designed to be unlikely to require lithium therapeutic drug monitoring (**TDM**"). Also, this MTD is risk mitigated for the purpose of treating fragile populations, such as Alzheimer's patients.

Lithium is a commonly prescribed drug for manic episodes in BPD type 1 as well as maintenance therapy of BPD in patients with a history of a manic episode. Lithium is also prescribed off-label for MDD, BPD and treatment of PTSD, among other disorders. Lithium was the first mood stabilizer approved by the United States Food and Drug Administration ("**FDA**") and is still a first-line treatment option (considered the "gold standard") but is underutilized perhaps because of the need for TDM. Lithium was the first drug that required TDM by regulatory authorities in product labelling because the effective and safe range of therapeutic drug blood concentrations is narrow and well defined for treatment of BPD when using lithium salts. Excursions above this range can be toxic, and below can impair effectiveness.

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 neurodegenerative, neurological and neuropsychiatric conditions. AL001 has the potential to deliver benefits of marketed lithium salts while mitigating or avoiding currently experienced toxicities associated with lithium. These results identified a safe and appropriate dose to explore the potential for AL001 to distribute more lithium to the brain but at lower systemic exposure, resulting in an improved safety profile compared to currently marketed lithium salts, thereby avoiding the disadvantages of currently approved lithium salts.

"This is excellent news for the 43+ million Americans afflicted with Alzheimer's, BPD, MDD and PTSD. The data support AL001 safety and tolerability and the potential for AL001 to provide a next-generation lithium therapy that does not require TDM. This can positively impact patient health and safety," said Stephan Jackman, Chief Executive Officer of Alzamend. "We look forward to further evaluating AL001 in two Phase II clinical trials for patients with mild to moderate Alzheimer's, of which we anticipate initiating both by the first quarter of 2024, and exploring the potential for AL001 for patients suffering from BPD, MDD and PTSD by submitting investigational new drug applications to the FDA for these indications by the end of 2023. We appreciate the extraordinary efforts of our colleagues and partners to identify a rigorously determined MTD from this multiple-ascending dose study."

About AL001 Phase IIA Study

The Phase IIA study evaluated the safety and tolerability of AL001 under multiple-dose, steady-state conditions. It determined the MTD in patients diagnosed with mild to moderate Alzheimer's disease and in healthy non-elderly and elderly subjects with adequate renal function. Lithium has been well characterized for safety and is approved/ marketed in multiple formulations for BPD. Lithium dosing for the multiple-ascending dose cohorts consisted of fractions of a usual dose for treatment of BPD. In each cohort, consisting of 6 active and 2 placebo subjects (as per randomization), multiple ascending doses were administered TID for 14 days, up to tolerability/safety limits. The safety profile was demonstrated to be benign at all dose levels, and so the selected dose level chosen for further development was based on avoidance of plasma drug concentrations associated in the medical literature with possible toxicity.

Based on the results from this study, Alzamend plans to initiate two future clinical trials at this MTD to determine relative increased lithium levels in the brain compared to a marketed lithium salt for Alzheimer's, BPD, MDD and PTSD, based on published mouse studies that predict that lithium can be given at lower doses for equivalent therapeutic benefit when treating with AL001. For example, the goal is to replace a 300 mg TID lithium carbonate dose for treatment of BPD with a 240 mg TID AL001 lithium equivalent, which represents a daily decrease of 20% of lithium given to a patient.

About Alzamend Neuro

Alzamend is an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of Alzheimer's, BPD, 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 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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