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): July 18, 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 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 3.01 REGULATION FD DISCLOSURE

On July 18, 2022, Alzamend Neuro, Inc. (the "**Company**"), issued a press release announcing that it received positive pre-investigational new drug response from the Food and Drug Administration for the AL001 treatment of bipolar disorder, major depressive disorder, and post-traumatic stress disorder. The Company expects topline data from AL001's phase IIA multiple ascending dose clinical trial for the treatment of dementia related to Alzheimer's, which trial commenced on May 5, 2022, to be available in December of 2022.

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 on July 18, 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: July 18, 2022

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

Exhibit 99.1

Alzamend Neuro Receives Positive Pre-IND Response from FDA for AL001 Treatment of Bipolar Disorder, Major Depressive Disorder and Post-Traumatic Stress Disorder

- ***Topline data expected in December 2022 from Phase IIA Multiple Ascending Dose Clinical Trial for AL001 Treatment of Dementia Related to Alzheimer's***
- ***Full data from Phase I first-in-human study demonstrated AL001 in plasma is bioequivalent to the marketed lithium carbonate product***

ATLANTA, GA, July 18, 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 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"). The FDA's response provides a path for Alzamend's planned clinical development of AL001 for the treatment of bipolar disorder, MDD and PTSD. AL001 is a novel lithium-delivery system; specifically, it is a lithium-salicylate-L-proline engineered ionic cocrystal under development as an oral treatment for patients with dementia resulting from mild, moderate or severe cognitive impairment caused by Alzheimer's. AL001 has the potential to deliver benefits of marketed lithium carbonate while mitigating or avoiding current toxicities associated with lithium.

Lithium was the first mood stabilizer and is still a first-line treatment option, but is underutilized, perhaps because of the need for therapeutic drug monitoring ("TDM") to assure safe and effective blood concentrations, and the availability of newer treatments. Lithium is a commonly prescribed drug for manic episodes in bipolar disorder as well as maintenance therapy of bipolar disorder in patients with a history of manic episodes. The primary target symptoms of bipolar disorder are mania and mood swings. Lithium is also prescribed off-label for MDD (often as an adjunct therapy), bipolar disorder (without a history of mania), and treatment of PTSD, among other neurodegenerative, neurological and neuropsychiatric disorders.

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 bipolar disorder when using lithium salts. Excursions above this range can be toxic. AL001 may enhance lithium distribution into target tissues in the central nervous system (brain) but at lower systemic exposures, resulting in an improved safety profile compared to lithium salts, including the possibility of mitigating lithium side effects and the current requirement for TDM.

In a Phase I relative bioavailability comparison of AL001 to lithium carbonate completed in March 2022, AL001 was shown to provide dose-normalized bioequivalent plasma pharmacokinetics and the observed safety profile was benign. A phase IIA, Multiple Ascending Dose ("MAD") clinical trial for the treatment of dementia related to Alzheimer's is currently underway. Alzamend plans to conduct further studies designed to enable it to ascertain comparative brain penetration and persistence of AL001 to lithium carbonate. These studies are expected to help predict observations seen in pharmacokinetic nonclinical findings to improve treatments in humans, including the potential for AL001 to exhibit lithium dose sparing properties that could mitigate lithium side effects and the current requirement for TDM in blood. 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 bipolar disorder when using lithium salts. Excursions above this range can be toxic. Since providing a greater concentration of lithium to the brain while minimizing the amount of the drug delivered to other organs can improve overall safety, AL001 has the potential to provide a safer product compared to currently marketed lithium salts.

“We appreciate the thorough and meaningful response from the FDA, which provides us with the information and clarity needed to submit IND applications to initiate clinical trials for AL001 for the treatment of bipolar disorder, MDD and PTSD,” said Stephan Jackman, Chief Executive Officer of Alzamend. “We are one step closer to substantiating that AL001 can potentially provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating over 40 million Americans suffering from Alzheimer’s, bipolar disorder, MDD, and PTSD. We appreciate the FDA’s recommendations, guidance, and other helpful advice. We plan to enhance our proposed clinical trial protocols and proceed accordingly.”

Based on the FDA’s written feedback, Alzamend anticipates filing the INDs for bipolar disorder, MDD and PTSD upon the completion of the current Phase IIA MAD study. This will allow Alzamend to initiate Phase II clinical trials for all three new indications.

About AL001 Phase IIA Study

The ongoing Phase IIA study is evaluating the safety and tolerability of AL001 under multiple-dose, steady-state conditions and is determining the maximum tolerated dose in patients diagnosed with mild to moderate Alzheimer’s. Lithium has been well characterized for safety and is approved/marketed in multiple formulations for bipolar disorder. Lithium dosing for the MAD cohorts consists of fractions of a usual dose for treatment of bipolar disorder. In each cohort, consisting of six active and two placebo patients (as per randomization), multiple ascending doses are being administered three times daily for 14 days under fasted conditions (at least one hour before or four hours after meals) up to tolerability/safety limits for this fragile Alzheimer’s population. The lithium and salicylate components of AL001 are to be given within the amounts already approved for use in patients for other indications. Up to 40 subjects will complete the Phase IIA trial. The maximum tolerated dose will then be used for further studies. The Phase IIA study commenced on May 5, 2022. More information can be found at www.clinicaltrials.gov, identifier: NCT05363293.

About AL001 Phase I Study

During this Phase 1 trial, participants received a single dose of AL001 containing lithium in an amount equivalent to 150 mg lithium carbonate, a dose proposed as likely appropriate for Alzheimer’s treatment when given three times daily. Currently, marketed lithium carbonate 300 mg capsules are often given three times daily when prescribed for manic episodes in bipolar disorder as well as for maintenance therapy of bipolar disorder in patients with a history of manic episodes. It can be difficult to control the appropriate dose of lithium salt formulations, including lithium carbonate, due to the small margin between effective and toxic blood levels, and therefore it can be challenging to avoid side effects or inadequate treatment outcomes.

Dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicated that AL001 at 150 mg lithium carbonate equivalent dosage is bioequivalent when dose-normalized to the marketed 300 mg lithium carbonate product and the shapes of the lithium plasma concentration versus time curves are highly similar. Based on the Phase I study results, it has been shown that dose-normalized systemic bioequivalence for lithium was established between AL001 and the marketed reference lithium carbonate 300 mg capsule. Findings of plasma bioequivalence to a marketed lithium product may allow Alzamend to design a development program that will potentially reduce the amount of new data generated to support approval. Demonstrated systemic bioequivalence also may have utility for AL001 when seeking approval for new indications as a benchmark for safety.

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 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.

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