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): August 17, 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 August 17, 2021, Alzamend Neuro, Inc. (the "**Company**") issued a press release to announce that it contracted Altasciences Company, Inc., to conduct a six-month Phase I relative bioavailability study for AL001 for dementia related to Alzheimer's disease in September 2021. The Phase I first-in-human study is for the purpose of determining potential clinically safe and appropriate dosing for AL001 in future studies. 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 August 17, 2021

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: August 17, 2021

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

Alzamend Neuro Announces It Has Contracted With Altasciences to Conduct a Phase I Relative Bioavailability Study for AL001 for Dementia Related to Alzheimer's Disease in September 2021

TAMPA, FL., August 17, 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 contracted Altasciences to conduct a six-month Phase I relative bioavailability study for AL001 for dementia related to Alzheimer's disease in September 2021. The Phase I first-in-human study is for the purpose of determining potential clinically safe and appropriate dosing for AL001 in future studies. AL001 is a lithium-delivering ionic cocrystal under development as an oral treatment for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer's disease.

"We are very excited about this partnership and have full confidence in Altasciences' ability to execute our Phase I clinical study," said Stephan Jackman, Chief Executive Officer of Alzamend. "We believe AL001 could potentially provide clinicians with a major improvement over current lithium-based treatments and may constitute a means of treating Alzheimer's and other neurodegenerative diseases and psychiatric disorders. We look forward to providing more details on the timeline following the commencement of the Phase I clinical study for AL001."

Overview of the Phase I Clinical Study

The Phase I study will investigate the pharmacokinetics (the movement of drug through the body) of lithium following single dose of AL001 (the "study drug") compared to a typical single dose of a marketed 300 mg immediate-release lithium carbonate capsule (the "comparator" currently indicated to treat mood disorders) in healthy male and female subjects. The lithium and salicylate components of AL001 will be given within the amounts already approved for use in patients. The purpose of the research study is to test the safety, tolerability, and bioavailability (how much and when drug gets in the body) of the study drug, AL001, compared to the currently marketed formulation of the comparator, lithium carbonate.

About AL001

AL001 is a patented ionic cocrystal technology delivering lithium via a therapeutic crystal-engineered combination of lithium, proline and salicylate, known as AL001 or LiProSal, through two royalty-bearing exclusive worldwide licenses from the University of South Florida Research Foundation, Inc.

Based on preclinical data, AL001 treatment prevents cognitive deficits, depression, and irritability in APPSWE/PS1dE9 mice, and has shown an improvement of associative learning and memory and irritability compared with lithium carbonate treatments, supporting the potential of this lithium formulation for the treatment of Alzheimer's disease and psychiatric disorders. Lithium has been marketed for more than 35 years and human toxicology regarding lithium use has been well characterized, potentially allowing Alzamend to rely upon this existing data, potentially reducing the regulatory burden for safety data.

About Alzamend Neuro

We are an early clinical-stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's disease. 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 crystal-engineered combination of lithium, proline and salicylate, and AL002 – a patented therapeutic mutant peptide sensitized cell-based therapeutic vaccine that is targeted to augment the ability of a patient's immune system to combat Alzheimer's disease. Both of our product candidates are licensed from the University of South Florida Research Foundation, Inc. pursuant to royalty-bearing exclusive worldwide licenses.

About AltaScience

Altasciences is an integrated drug development solution company offering pharmaceutical and biotechnology companies a proven, flexible approach to preclinical and clinical pharmacology studies, including formulation, manufacturing, and analytical services. For over 25 years, Altasciences has been partnering with sponsors to help support educated, faster, and more complete early drug development decisions. Altasciences' integrated, full-service solutions include preclinical safety testing, clinical pharmacology and proof of concept, bioanalysis, program management, medical writing, biostatistics, clinical monitoring, and data management, all customizable to specific sponsor requirements. Altasciences helps sponsors get better drugs to the people who need them, faster.

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