

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 28, 2021

ALZAMEND NEURO, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

001-40483
(Commission File Number)

81-1822909
(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 July 28, 2021, Alzamend Neuro, Inc. (the “**Company**”) issued a press release to announce that it has received a U.S. Food and Drug Administration “study may proceed” letter for a Phase 1 clinical study under the Company’s Investigational New Drug application for AL001, a patented lithium-based ionic cocrystal oral therapy for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer’s disease.

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 July 28, 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: July 28, 2021

/s/ Henry Nisser

Henry Nisser

Executive Vice President and General Counsel



Alzamend Neuro Receives FDA “Study May Proceed” Letter for Phase 1 Clinical Study Under its Investigational New Drug Application for AL001 for Dementia Related to Alzheimer’s Disease

TAMPA, FL., July 28, 2021--Alzamend Neuro, Inc. (Nasdaq: ALZN) (“**Alzamend**”), an early clinical-stage stage biopharmaceutical company focused on developing novel products for the treatment of neurodegenerative diseases and psychiatric disorders, today announced receipt of U.S. Food and Drug Administration (“**FDA**”) study may proceed letter for a Phase 1 study under the Company’s Investigational New Drug application for AL001, a lithium-based ionic cocrystal oral therapy for patients with dementia related to mild, moderate, and severe cognitive impairment associated with Alzheimer’s disease.

“We are grateful to receive this timely, favorable response from the FDA to initiate a Phase 1 trial with AL001,” said Stephan Jackman, the Chief Executive Officer of Alzamend. “We are advancing the process and expect that the first patient will be dosed in September 2021.”

About AL001

AL001 is a patented ionic cocrystal technology delivering a therapeutic 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. With our product candidates, we aim to bring treatments or cures to market at a reasonable cost as quickly as possible. Our current pipeline consists of two novel therapeutic drug candidates, AL001 – a patented ionic cocrystal technology delivering 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 Disease. 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
