

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 16, 2023

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.)

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 2.02 Results of Operations and Financial Condition

On March 16, 2023, Alzamend Neuro, Inc. (the "Company") issued a press release announcing its financial results for its third quarter ended January 31, 2023 (the "Press Release"). A copy of the Press Release is attached hereto as **Exhibit 99.1** and is incorporated by reference herein.

The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. The information contained in this Item 2.02 and in the Press Release furnished as Exhibit 99.1 to this Current Report on Form 8-K shall not be incorporated by reference into any filing with the Securities and Exchange Commission made by the Company whether made before or after the date hereof, except as expressly set forth by specific reference in such a filing.

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.

Where You Can Find Additional Information

Investors and security holders will be able to obtain documents filed with the Securities and Exchange Commission free of charge at the Commission's website,

www.sec.gov. Security holders may also read and copy any reports, statements and other information filed by the Company with the Commission, at the SEC public reference room at 100 F Street, N.E., Washington D.C. 20549. Please call the Commission at 1-800-SEC-0330 or visit the Commission's website for further information on its public reference room.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits:

Exhibit No.	Description
99.1	Press Release issued on March 16, 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 16, 2023

/s/ David J. Katzoff
David J. Katzoff
Chief Financial Officer



Alzamend Neuro Reports Third Fiscal Quarter Financial Results and Provides a Business Update

- *Company had \$7.4 Million Cash at January 31, 2023*
- *Additional Non-Dilutive Capital via Note Receivable of \$14.8 Million Expected in December 2023*
- *Initiation of Phase I/IIA Clinical Trial for ALZN002 to Treat Mild to Moderate Dementia of the Alzheimer's Type Expected in March 2023*
- *Topline Data from Phase IIA Multiple Ascending Dose Clinical Trial for AL001 in Treatment of Dementia Related to Alzheimer's Expected in June 2023*

ATLANTA, GA, March 16, 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 financial results for the third quarter ended January 31, 2023 and provided an update on its clinical operations.

"We strongly believe that AL001's patented ionic cocrystal technology and the ALZN002 patient-specific immunotherapeutic vaccine candidate have the potential of treating over 40 million American suffering from Alzheimer's and other neurodegenerative diseases and psychiatric disorders", said Stephan Jackman, Chief Executive Officer of Alzamend. "We look forward to receiving topline data in June 2023 from our Phase IIA multiple ascending dose clinical trial for AL001 for the treatment of Dementia related to Alzheimer's. Additionally, we are about to initiate a Phase I/IIA clinical trial for ALZN002 to treat mild to moderate dementia of the Alzheimer's type, which is expected to occur by the end of this month."

Financial Results for Quarter Ended January 31, 2023

- At January 31, 2023, cash was \$7.4 million, and working capital was \$5.8 million.
- Net loss for the three months ended January 31, 2023 was \$5.4 million, or \$0.06 per share. This compares to a net loss of \$2.6 million, or \$0.03 per share, for the same period in the prior year. The net loss increased compared to the prior period due primarily to a significant increase in our research and development ("R&D") activities for a Phase IIA program of AL001 in Alzheimer's and activities relating to the filing of an investigational new drug ("IND") application to conduct a Phase I/IIA program of ALZN002 in Alzheimer's.
- Net cash used in operations was \$6.7 million during the nine months ended January 31, 2023.
- R&D expenses for the three months ended January 31, 2023 were \$2.9 million. This compares to \$0.9 million for the same period in the prior year. R&D expenses increased compared to the prior period due primarily to increased activities and expenses related to clinical and pre-clinical studies and support functions.

- General and administrative ("G&A") expenses for the three months ended January 31, 2023 were \$2.5 million. This compares to \$1.7 million for the same period in the prior year. G&A expenses increased compared to the prior period due primarily to increased marketing fees and stock-based compensation.

"We expect to receive \$14.8 million of cash in 2023, as a note receivable issued to us from a prior sale of our common stock has a maturity date of December 31, 2023. While no assurances can be given that the note issuer will pay on or before the maturity date, the receipt of such additional capital would be non-dilutive, and we anticipate utilizing such capital to file INDs for bipolar disorder, MDD, and PTSD, as well as conducting Phase II clinical trials for the respective indications", said Mr. David Katzoff, Chief Financial Officer of Alzamend. "The net proceeds (~\$13.1 million) from our initial public offering in June 2021 was intended to cover the expenses for Phases I for AL001 and ALZN002. We have been able to accomplish a lot more by being innovative and excellent stewards of the capital, thereby maintaining a low burn rate and capping our workforce to four full-time and three part-time employees."

Clinical Operations Update

AL001

AL001 is a patented ionic cocrystal technology delivering lithium via a therapeutic crystal-engineered combination of lithium, L-proline and salicylate, known as AL001 or LiProSal. Alzamend previously completed a Phase I first-in-human trial to determine the pharmacokinetics, safety and tolerability of AL001. During this Phase I trial, participants received a single dose of AL001 containing lithium in an amount equivalent to 150 mg lithium carbonate; at the dose proposed deemed appropriate for Alzheimer's treatment when given three times daily. Currently, marketed lithium carbonate 300 mg are given three times daily when prescribed for manic episodes in bipolar disorder as well as maintenance therapy of bipolar disorder in patients with a history of manic episodes. The data affirmed that dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicated that AL001 at 150 mg dosage is bioequivalent to the marketed 300 mg lithium carbonate product and the shapes of the lithium plasma concentration versus time curves are similar.

Findings of plasma bioequivalence to a marketed lithium product may allow Alzamend to reduce the scope or eliminate the need for Phase 2 and Phase 3 studies of efficacy and/or safety of AL001 in such indications as bipolar/affective disorders in which lithium efficacy has been established. Bioequivalence may have utility for AL001 when seeking approval for the indications of currently marketed lithium products, and for new indications as a benchmark for safety.

The ongoing Phase IIA clinical trial, which was initiated in May 2022, is evaluating 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 adult subjects. Lithium has been well characterized for safety and is approved/marketed in multiple formulations for bipolar affective disorders. Up to 40 subjects will complete the Phase IIA trial. The maximum tolerated dose will then be used for further studies in Alzheimer's, bipolar disorder, MDD and PTSD. Topline data for this clinical trial is expected in June 2023.

AL002

ALZN002 is a proprietary "active" immunotherapy product, which means it is produced by each patient's immune system. It consists of autologous dendritic cells ("DCs"), which are activated white blood cells taken from each individual patient that are then engineered outside of the body to attack Alzheimer's-related amyloid-beta proteins. These DCs are pulsed with a novel amyloid-beta peptide (E22W) designed to bolster the ability of the patient's immune system to combat Alzheimer's; the goal of this treatment

approach is to foster tolerance to treatment for safety purposes while stimulating the immune system to reduce the brain's beta-amyloid protein burden, resulting in reduced Alzheimer's signs and symptoms.

The ALZN002 DC treatment is, by definition, an individual-patient-specific therapy since these autologous DCs are administered to the same patient from whom they were removed. Each patient will undergo leukapheresis, i.e., removal and return to the body of white blood cells. This procedure will isolate each patient's peripheral blood monocytes from the obtained white blood cells. These are subsequently differentiated outside the body into DCs that are engineered to induce immunogenicity (search and destroy capability) towards amyloid, the protein associated with Alzheimer's in the patient's body, but to be otherwise tolerated as natural to the body to avoid adverse side effects.

Compared to passive immunization treatment approaches that use foreign blood products (such as monoclonal antibodies), active immunization with ALZN002 is anticipated to offer a more robust and long-lasting effect on the clearance of amyloid. This is expected to provide a safe and effective treatment for Alzheimer's sufferers that requires considerably less frequent treatment visits compared to passive immunity approaches.

Alzamend expects to initiate a Phase I/Phase IIA clinical trial for ALZN002 to treat mild to moderate dementia of the Alzheimer's type by the end of March 2023. The purpose of this trial is to assess the safety, tolerability, and efficacy of multiple ascending doses of ALZN002 compared with that of placebo in 20-30 subjects with mild to moderate dementia of the Alzheimer's type. The primary goal of this clinical trial is to determine an appropriate dose of ALZN002 for treatment of patients with Alzheimer's in a larger Phase IIB efficacy and safety clinical trial, which Alzamend expects to initiate within three months of receiving data from the initial trial.

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 ALZN002 - 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

Alzamend Neuro, Inc. Condensed Balance Sheets (Unaudited)

	January 31, 2023	April 30, 2022
ASSETS		
CURRENT ASSETS		
Cash	\$ 7,375,841	\$ 14,063,811
Prepaid expenses and other current assets	546,303	349,723
Prepaid expenses - related party	494,668	-
TOTAL CURRENT ASSETS	8,416,812	14,413,534
Property, plant and equipment, net	85,166	102,909
TOTAL ASSETS	\$ 8,501,978	\$ 14,516,443

LIABILITIES AND STOCKHOLDERS' EQUITY

CURRENT LIABILITIES

Accounts payable and accrued liabilities	\$ 2,642,473	\$ 1,162,850
Related party payable	-	2,082
TOTAL CURRENT LIABILITIES	2,642,473	1,164,932
TOTAL LIABILITIES	2,642,473	1,164,932

COMMITMENTS AND CONTINGENCIES

STOCKHOLDERS' EQUITY

Convertible Preferred stock, \$0.0001 par value: 10,000,000 shares authorized; Series A Convertible Preferred Stock, \$0.0001 stated value per share, 1,360,000 shares designated; nil 0 issued and outstanding as of January 31, 2023 and April 30, 2022

Common stock, \$0.0001 par value: 300,000,000 shares authorized; 96,427,624 and 95,481,790 shares issued and outstanding as of January 31, 2023 and April 30, 2022, respectively	9,642	9,548
Additional paid-in capital	61,500,292	57,419,753
Note receivable for common stock – related party	(14,883,295)	(14,883,295)
Accumulated deficit	(40,767,134)	(29,194,495)
TOTAL STOCKHOLDERS' EQUITY	5,859,505	13,351,511
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	\$ 8,501,978	\$ 14,516,443

Alzamend Neuro, Inc.
Condensed Statements of Operations
(Unaudited)

	For the Three Months Ended January 31,		For the Nine Months Ended January 31,	
	2023	2022	2023	2022
OPERATING EXPENSES				
Research and development	\$ 2,888,847	\$ 873,653	\$ 5,797,789	\$ 3,540,111
General and administrative	2,534,665	1,682,913	5,767,668	4,906,628
Total operating expenses	<u>5,423,512</u>	<u>2,556,566</u>	<u>11,565,457</u>	<u>8,446,739</u>
Loss from operations	<u>(5,423,512)</u>	<u>(2,556,566)</u>	<u>(11,565,457)</u>	<u>(8,446,739)</u>
OTHER EXPENSE, NET				
Interest expense	(2,062)	(16,299)	(7,182)	(45,922)
Total other expense, net	<u>(2,062)</u>	<u>(16,299)</u>	<u>(7,182)</u>	<u>(45,922)</u>
NET LOSS	<u>\$ (5,425,574)</u>	<u>\$ (2,572,865)</u>	<u>\$ (11,572,639)</u>	<u>\$ (8,492,661)</u>
Basic and diluted net loss per common share	<u>\$ (0.06)</u>	<u>\$ (0.03)</u>	<u>\$ (0.12)</u>	<u>\$ (0.09)</u>
Basic and diluted weighted average common shares outstanding	<u>98,326,175</u>	<u>94,165,225</u>	<u>97,765,471</u>	<u>89,484,601</u>

Alzamend Neuro, Inc.
Condensed Statements of Cash Flows
(Unaudited)

	For the Nine Months Ended January 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (11,572,639)	\$ (8,492,661)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	17,743	-
Interest expense - debt discount	-	12,770
Stock-based compensation to employees and consultants	3,091,299	3,150,801
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(196,580)	344,493
Prepaid expenses related party	492,584	-
Accounts payable and accrued expenses	1,479,623	(67,040)
)Net cash used in operating activities	<u>(6,687,970)</u>	<u>(5,051,637)</u>
Cash flows from financing activities:		
Proceeds from the issuance of common stock and warrants - related party, net	-	2,000,000
Proceeds from stock option exercise	-	1,200
Proceeds from initial public offering, net of underwriters' discounts and commissions and issuance costs	-	12,911,456
Net cash provided by financing activities	<u>-</u>	<u>14,912,656</u>
Net (decrease) increase in cash	(6,687,970)	9,861,019
Cash at beginning of period	14,063,811	1,929,270
Cash at end of period	<u>\$ 7,375,841</u>	<u>\$ 11,790,289</u>

Supplemental disclosures of cash flow information:

Non-cash financing activities:		
Fair value of warrants issued in connection with March 2021 securities purchase agreement, related party	\$ -	\$ 4,799,742
Fair value of warrants issued in connection with IPO	\$ -	\$ 461,877
Issuance of common stock on conversion of note	\$ -	\$ 378,373
Issuance of common stock for related party payable	\$ 989,334	\$ -