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): May 15, 2024

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 ☒

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.

Alzamend Neuro, Inc. (the "**Company**") updated its investor presentation (the "**Corporate Presentation**"), which is used to conduct meetings with investors, stockholders and analysts and at investor conferences, which may contain nonpublic information. A copy of the Corporate Presentation, which is furnished herewith as **Exhibit 99.1**, is incorporated by reference herein. The Corporate Presentation provides, among other things, an overview of the Company's therapeutic drugs for the treatment of neurodegenerative diseases and psychiatric disorders, including Alzheimer's.

In accordance with General Instruction B.2 of Form 8-K, the information under this item and **Exhibit 99.1** 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	Corporate Presentation
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: May 15, 2024

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

Exhibit 99.1

Alzamend Neuro, Inc.

Corporate Presentation

Alzamend®

May 2024

SAFE HARBOR STATEMENT

This presentation and other written or oral statements made from time to time by representatives of Alzamend Neuro, Inc. (the "Company" or "Alzamend") contain "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. Forward-looking statements reflect the current view about future events. Statements that are not historical in nature, such as forecasts for the industry in which we operate, and which may be identified by the use of words like " expects," "assumes," "projects," "anticipates," "estimates," "we believe," "could be," "future,"" or the negative of these terms and other words of similar meaning, are forward-looking statements. Such statements include, but are not limited to, statements contained in this presentation relating to our business, business strategy, expansion, growth and product candidates and the timing of their development, sales and marketing strategy and capital outlook. Forward-looking statements are based on management's current expectations and assumptions regarding our business, the economy and other future conditions and are subject to inherent risks, uncertainties and changes of circumstances that are difficult to predict and may cause actual results to differ materially from those contemplated or expressed. We caution you therefore against relying on any of these forward-looking statements.

These risks and uncertainties include those risk factors discussed in Part I, "Item 1A. Risk Factors" of our Annual Report on Form 10-K for the fiscal year ended April 30, 2023 (the "2023 Annual Report") and other information contained in subsequently filed current and periodic reports, each of which is available on our website and on the Securities and Exchange Commission's website (www.sec.gov). Any forward-looking statements are qualified in their entirety by reference to the risk factors discussed in the 2023 Annual Report. Should one or more of these risks or uncertainties materialize (or in certain cases fail to materialize), or should the underlying assumptions prove incorrect, actual results may differ significantly from those anticipated, believed, estimated, expected, intended or planned.

Important factors that could cause actual results to differ materially from those in the forward-looking statements include: risks related to performing clinical studies; the ability to initiate and complete clinical studies and report data therefrom; whether the results from clinical studies will validate and support the safety and efficacy of our product candidates; competition from other products; risks in product development; the ability to protect our intellectual property rights; impact of any litigation or infringement actions brought against us; market acceptance if we can commercialize our product candidates; inability to raise capital to fund clinical trials; and changes in government regulation.

Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We cannot guarantee future results, levels of activity, performance or achievements. Except as required by applicable law, including the securities laws of the United States, we do not intend to update any of the forward-looking statements to conform these statements to actual results.

All forecasts are provided by management in this presentation and are based on information available to us at this time and management expects that internal projections and expectations may change over time. In addition, the forecasts are based entirely on management's best estimate of our future financial performance given our product candidate development and market opportunities.

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INTRODUCTION

Company Overview

NASDAQ: ALZN

Industry	Biopharmaceutical
Sector	Small Molecule / Cell Therapy
Founded	2016
IPO	June 15, 2021
Last Reported Cash	$280k (Per our 10-Q filed on March 25, 2024)
Location	Atlanta, Georgia (Corporate Headquarters)

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Company Overview

Lead Drug Candidate – Ionic Cocrystal of Lithium (AL001)

Multiple Indications	Potential Replacement to Marketed Lithium Therapies	Market Opportunity
➢ AL001 is a **patented ionic cocrystal of lithium** for the potential treatment of **Alzheimer's disease**, **Bipolar Disorder** ("BD"), **Major Depressive Disorder** ("MDD") and **Post-Traumatic Stress Disorder** ("PTSD") ➢ **Completed a Phase I Relative Bioavailability Study** in healthy human subjects in **March 2022** and **Reported Topline data of a Phase IIA Multiple Ascending Dose Study** in patients with mild to moderate Alzheimer's Disease and Healthy Adult Subjects in **June 2023** ➢ **Received "Study May Proceed"** notifications in **2H 2023** from the FDA to Initiate Phase II Clinical Trials for treatment of **Bipolar Disorder, MDD, PTSD** ➢ **Anticipate initiating Phase II clinical study** in **BD** patients in **2H 2024** ➢ **Anticipate initiating Phase II clinical studies** in **Alzheimer's**, **MDD** and **PTSD** patients in **2025**	➢ **Phase I and IIA Studies confirmed AL001** as a potential replacement to marketed lithium therapies ➢ **AL001** providing lithium at a lithium carbonate equivalent dose of 150 mg **is bioequivalent to** a marketed 300 mg **lithium carbonate** capsule ➢ **Identified a maximum tolerated dose** ("MTD"), providing lithium at a lithium carbonate equivalent dose of 240-mg, designed to be **unlikely to require therapeutic drug monitoring** ("TDM") ➢ **Safety aspects of AL001** development may qualify for (505)(b)(2) pathway for FDA approval	➢ **43.5 million** U.S. patient population ➢ **664 million** global patient population

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Company Overview

Reference to AL001: Current Marketed Lithium – Lithium Carbonate

Usage For BD, MDD, PTSD	Challenges	Published Clinical Efficacy Studies For Alzheimer's
➢ **Approved** by the **FDA** for **BD** and **utilized off-label** for **MDD**, **PTSD**, and other neurodegenerative, neurological and neuropsychiatric disorders ➢ First mood stabilizer and first-line treatment for BD (Considered the gold standard treatment) ➢ **524 clinical trials** conducted for multiple indications (www.clinicaltrials.gov) ➢ **5,444 published research articles** (www.pubmed.gov)	➢ Narrow therapeutic window ➢ Chronic Toxicity ➢ Adverse Effects ➢ Requires "TDM"	➢ Forlenza, 2011[1]: Lithium significantly decrease CSF concentrations of P-tau and better performance on the cognitive subscale of the Alzheimer's Disease Assessment Scale ("ADAS-cog") (1). Forlenza, 2011: https://pubmed.ncbi.nlm.nih.gov/21525519/ ➢ Matsunaga, 2015[2]: Lithium significantly decreased cognitive decline as compared to placebo (2). Matsunaga, 2015: https://pubmed.ncbi.nlm.nih.gov/26402004/ ➢ Devanand, 2017[3]: All patients improved to varying degrees as determined by clinical judgment and/or objective rating scales, Clinical Global Impression Severity ("CGI-S") and Change ("CGI-C") scales, and the Neuropsychiatric Inventory ("NPI") (3). Devanand, 2017: https://pubmed.ncbi.nlm.nih.gov/27819842/

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INTRODUCTION

Company Overview

Product Candidate	Indication	Pre-Clinical	Phase I	Phase II	Phase III	FDA Approval
AL001	• Alzheimer's Disease	→	→	• Reported Topline data for the Phase IIA MAD study in June 2023 • Anticipate initiating a Phase II clinical studies in Alzheimer's patients in 2025		
	• Bipolar Disorder	→	→	• Received "Study May Proceed" notification from the FDA in September 2023 to Initiate a Phase II Clinical Trial • Anticipate initiating a Phase II clinical studies in BD patients in 2024		
	• Major Depressive Disorder	→	→	• Received "Study May Proceed" notification from the FDA in November 2023 to Initiate a Phase II Clinical Trial • Anticipate initiating a Phase II clinical studies in MDD patients in 2025		
	• Post -Traumatic Stress Disorder	→	→	• Received "Study May Proceed" notification from the FDA in December 2023 to Initiate a Phase II Clinical Trial • Anticipate initiating a Phase II clinical studies in PTSD patients in 2025		
ALZN002	• Alzheimer's Disease	→	→	• Initiated Phase I/IIA Clinical Trial in March 2023, paused in February 2024 and expected to resume in 2H 2024		

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INTRODUCTION

Company Overview

Company History

Clinical-stage biopharmaceutical company dedicated to:

- Researching, developing and commercializing preventions, treatments and cures for **Alzheimer's Disease, Bipolar Disorder, Major Depressive Disorder,** and **Post-Traumatic Stress Disorder** via the **two therapeutics** licensed from the **University of South Florida Research Foundation, Inc.**, one of the top 20 institutions in the nation for patented research and their portfolio of proprietary solutions.

Current Pipeline

AL001 (aka LISPRO):

- a **patented ionic cocrystal technology** delivering a therapeutic combination of **lithium**, **salicylate** and **proline** for the treatment of **Alzheimer's' Disease**, **BD**, **MDD** and **PTSD**

ALZN002 (aka E22W):

- a **cell-based therapeutic vaccine** that seeks to **restore** the ability of the patients' **immunological system** to combat Alzheimer's Disease.

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Alzheimer's Disease

Alzheimer's Disease:

Alzheimer's Disease is an **irreversible, progressive brain disorder** that **slowly destroys memory** and **cognitive skills**, and eventually the **ability to carry out the simplest tasks**.

In most people with Alzheimer's Disease, symptoms first appear in their early to mid-60's. Estimates vary, but per the Alzheimer's association, nearly **7 million Americans** may have Alzheimer's Disease, considered by many as **"the most feared" disease**. **Between 2000 and 2019,** deaths from heart disease have **decreased 7.3%** while deaths from Alzheimer's Disease have **increased 145%**

Alzheimer's Disease has **no current cure**, and only few treatments for symptoms are available today while research continues.

Key Statistics:

7th leading cause of death in the United States

13 million Americans are projected to be living with Alzheimer's Disease by 2050

In 2023, **Alzheimer's** and other **dementias** will cost the nation **$345 Billion**

Lithium and Alzheimer's:

Published clinical efficacy trials have reported that treatment with **lithium carbonate** have resulted in **reduction of biomarkers, irritability,** and **cognitive decline,** in patients with Alzheimer's.

AIZN002 and Alzheimer's:

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.**

https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf

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Bipolar Disorder

Bipolar Disorder:

Bipolar Disorder is a mental illness that causes unusual shifts in a person's **mood, energy, activity levels, and concentration**.

The **three primary types** of bipolar disorders are bipolar I disorder, bipolar II disorder, and cyclothymic disorder.

- **Bipolar I:** Characterized by episodes of mania that last at least seven days and may require hospitalization.
- **Bipolar II:** Defined by a pattern of depressive and hypomanic episodes. Hypomania is a mood elevation that increases energy, agitation, and pressured speech.
- **Cyclothymic disorder:** More frequent shifts between mood swings, which is called rapid cycling. The highs are consistent with hypomania symptoms and the lows are mild to moderate depression.

Key Statistics:

An estimated **7 Million** adults in the US and over **45 Million** globally experience **Bipolar Disorder** each year

Of adults who live with **Bipolar Disorder**, almost **83%** experience significant disruption in their physical or mental abilities

The risk of **suicide** is extremely high in people with bipolar disorder with **15% to 17% committing suicide**

Lithium and BD:

Lithium was the **first mood stabilizer approved by the FDA** and is still **a first-line treatment option** (considered the "**gold standard**") for BD but is underutilized perhaps because of the need for "TDM" and patent expiration.

https://www.betterhelp.com/advice/bipolar/bipolar-disorder-statistics-how-many-people-does-it-affect/
https://www.singlecare.com/blog/news/bipolar-disorder-statistics/

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Major Depressive Disorder

Major Depressive Disorder:

Major Depressive Disorder, commonly known as **clinical depression**, is one of the most common mental disorders worldwide. Many different factors can contribute to a person's depressive state and depression is often an **overlapping diagnosis** along with **other medical conditions and/or mental disorders.**

The most prominent **symptoms** of major depression are a **severe** and **persistent low mood, profound sadness**, or a **sense of despair.** A major depressive episode (MDE) is a time-period characterized by symptoms of **major depression.**

Depression is the cause of over **two-thirds** of the **30,000 reported suicides** in the U.S. each year.

Key Statistics:

An estimated **21 Million** adults in U.S. had at least one **major depressive** episode in 2021. This number represented **8.3%** of all U.S. adults.

An estimated **5.0 million adolescents aged 12 to 17** in the United States had at least one major depressive episode. This number represented **20.1% of the U.S. population aged 12 to 17.**

Lithium and MDD:

Although lithium products do not have an FDA-approved indication for MDD, it has been **utilized off-label for MDD**.

While a wide variety of medications have been used historically for augmentation of an antidepressant in MDD, lithium is one of the few agents that has **demonstrated efficacy in multiple randomized controlled trials.**

https://www.nimh.nih.gov/health/statistics/major-depression
https://www.dbsalliance.org/education/depression-statistics
https://www.simplepsy.com/blog/mental-depression-statistics/

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Post-Traumatic Stress Disorder

Post-Traumatic Stress Disorder:

PTSD is a **mental and behavioral disorder** that can develop because of exposure to a **traumatic event**, such as sexual assault, warfare, traffic collisions, child abuse, domestic violence, or other **threats on a person's life.**

Symptoms may include disturbing **thoughts, feelings, or dreams** related to the events, **mental or physical distress** in response to trauma-related cues, attempts to avoid trauma related cues, alterations in the way a person thinks and feels, and an increase in the fight-or-flight response.

These symptoms last for more than a month after the event. A person with **PTSD** is at a **higher risk of suicide** and intentional self-harm.

https://www.nimh.nih.gov/health/topics/post-traumatic-stress-disorder-ptsd
https://www.ptsd.va.gov/understand/common/common_adults.asp
https://www.nhs.uk/mental-health/conditions/post-traumatic-stress-disorder-ptsd/overview/

Key Statistics:

About **5 out of every 100 adults** (or 5%) in the U.S. has PTSD in **any given year**. In 2020, about **13 million** Americans had PTSD.

Veterans are more likely to have PTSD than **civilians.** Veterans who **deployed** to a **war zone** are also more likely to have PTSD than those who did not deploy.

Lithium and PTSD:

Although lithium products do not have an FDA-approved indication for PTSD, it has been **utilized off-label for PTSD**.

Treatment with **low doses** (300-600 mg/day) of **lithium carbonate** have been reported to **provide effective treatment** in **reduction of inappropriate anger, irritability, anxiety,** and **insomnia** in patients with PTSD.

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GENERAL SCIENTIFIC OVERVIEW

Overview of Our Science

Therapeutic Drug	Synopsis	Strength	Status
AL001	• Use of patented ionic cocrystal technology delivering a therapeutic combination of Lithium, Proline, and Salicylate • Lithium as a treatment of agitation and other possible symptoms in patients with indication of Alzheimer's Disease • Other potential indications: Dementia, Amyotrophic Lateral Sclerosis ("ALS"), Huntington's Disease, multiple sclerosis, Parkinson's Disease and traumatic brain injury ("TBI"), to more psychiatric conditions such as BD, MDD, mania, PTSD and suicidality	• Exclusive license for ionic cocrystal delivery system to treat Alzheimer's Disease • Potential for "breakthrough therapy" designation from FDA • Seeking a 505(b)(2) clinical trial pathway from FDA • Formulation may importantly expand the range of therapeutic categories amenable to lithium treatments, with enhanced safety • Has the potential of becoming the replacement for all lithium therapies on the market	• Reported Topline data of Phase IIA Multiple Ascending Dose Clinical Trial in June 2023.(www.clinicaltrials.gov, identifier: **NCT05363293**) • Received "Study May Proceed" notification from the FDA in 2H 2023 to Initiate a Phase II Clinical Trial to treat Bipolar Disorder, Major Depressive Disorder and Post-Traumatic Stress Disorder • Anticipate initiating a Phase II Clinical trial in patients with BD in 2H 2024 • Anticipate initiating a Phase II Clinical trial in patients with Alzheimer's, MDD, and PTSD in 2025
ALZN002	• A patented method using a mutant peptide sensitized cell as a cell-based therapeutic vaccine that reduces beta-amyloid plaque and seeks to restore the ability of the patient's immunological system to combat Alzheimer's Disease	• Adjuvant-free therapeutic vaccine designed for the treatment and prophylactics of Alzheimer's Disease • Potential for "breakthrough therapy" designation from FDA • Antibody responses induced after one inoculation (Pre-Clinical) and lasted for 4 months • Inflammation cytokines like IL1 and TNF.alpha, which are considered being related to inflammation didn't increase with antibody level increase	• Phase I/IIA Clinical Trial Initiated in March 2023 (www.clinicaltrials.gov, identifier: **NCT05834296**), paused in February 2024 and expected to resume in 2H 2024

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OUR SCIENCE - CLINICAL

AL001 Phase I Trial

Study No.	Study Title	Description	Status
AL001-ALZ01 (US)	A randomized, balanced, Phase I, single-dose, open-label, two-treatment, two-period, two sequence, crossover, relative bioavailability study to investigate lithium pharmacokinetics and safety of AL001 formulation compared to a marketed immediate release lithium carbonate formulation in healthy subjects.	• To assess the relative bioavailability of the AL001 lithium formulation relative to a marketed lithium carbonate formulation in healthy subjects for the purpose of determining potential clinically safe and effective AL001 dosing in future studies. • To characterize safety and tolerability of the tested formulations under the conditions of this study.	Completed

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Select Results from Phase I Trial

Safety/Tolerability: Primary Endpoint Met

- AL001 was shown to be **safe** and **well-tolerated** in healthy adult subjects
- **No serious adverse events** and **no deaths** were reported during the trial
- The **safety profiles** of both **AL001** and the marketed **lithium carbonate capsule** were **benign**
- **No clinically significant abnormal findings in electrocardiograms were noted** during the trial
- **AL001 salicylate plasma concentrations** were observed to be **well tolerated** and **consistently within safe limits**
- Dose-adjusted relative bioavailability analyses of the rate and extent of lithium absorption in plasma indicated that **AL001 1050 mg** (lithium content equivalent to150 mg lithium carbonate) is **bioequivalent to a marketed 300 mg lithium carbonate capsule** and the **shapes of the lithium plasma concentration versus time curves** are **similar**

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AL001 Phase IIA Trial

Study No.	Study Title	Description	Status

AL001-ALZ02 (US)	A Multiple-dose, Steady-state, Double-blind, Ascending Dose Safety, Tolerability, Pharmacokinetic Study of AL001 in Patients with Mild to Moderate Alzheimer's Disease and Healthy Adult Subjects	• **Primary:** To evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions in Alzheimer's subjects and healthy adult subjects
		• **Secondary:** To characterize the "MTD" of AL001 in subjects with mild to moderate Alzheimer's Disease and healthy adult subjects
		• **Exploratory:** To explore the difference in pharmacokinetic profile between the non-elderly vs. elderly subjects (healthy subjects only). For Alzheimer's Disease subject cohorts (Cohorts 1,2b, 3b, 4b, and 5b), determination of qualitative and quantitative evaluations of Alzheimer's Disease subject desirable characteristics for future Phase II and III clinical studies to:
		  • Facilitate recruitment into subsequent AL001 clinical trials
		  • Facilitate trial-adherence to completion of study requirements including treatment adherence
			• Reported Topline data of Phase IIA Multiple Ascending Dose Clinical Trial in **June 2023**. (www.clinicaltrials.gov, identifier: **NCT05363293**)

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Topline Results from Phase IIA Trial

Identify Maximum Tolerated Dose: Established

- **Identified dose of lithium** at a lithium carbonate equivalent dose of **240 mg 3-times a day** ("TID"), is designed to be **unlikely** to require **lithium TDM**
- **No serious adverse events** and **no deaths** were reported during the trial
- **MTD is risk mitigated** for the purpose of **treating fragile populations**, such as **Alzheimer's patients**
- **Goal** is to replace a **300 mg TID lithium carbonate dose** for treatment of **BD** with a **240 mg TID AL001 lithium equivalent,** which represents a daily **decrease of 20% of lithium** given to a patient
- Results identified a **safe and appropriate dose** to explore the potential for AL001 to **distribute more lithium to the brain** but at a lower systemic exposure, resulting in an **improved safety profile** compared to **currently marketed lithium salts**

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ALZN002 Phase I/IIA Trial

Study No.	Study Title	Description	Status
ALZN002-01(US)	A Randomized, Double-blind, Placebo-controlled, Parallel group, Phase I/IIA Study to Assess the Safety, Tolerability, and Efficacy of Autologous Amyloid Beta Mutant Peptide-Pulsed Dendritic Cells (ALZN002) in Subjects with Mild-to-Moderate Dementia of the Alzheimer's Type	• **Primary:** • To assess the safety and tolerability of ALZN002 compared with placebo when administered as IV infusion and ID injection in subjects with mild to moderate AD • **Secondary:** • To evaluate the immunogenicity of ALZN002 specific to generation of anti-Aβ antibodies • To determine the effect of ALZN002 on Amyloid-Related Imaging Abnormalities (ARIA) as a putative biomarker of treatment safety • **Exploratory:** • To assess the utility of multiple immune biomarkers as surrogates for safety and efficacy of ALZN002. • To assess the preliminary efficacy of ALZN002 treatment on amyloid markers as observed by amyloid positron emission tomography (PET).	Phase I/IIA Clinical Trial Initiated in March 2023 (www.clinicaltrials.gov, identifier: **NCT05834296**), paused in February 2024 and expected to resume in 2H 2024

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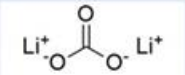
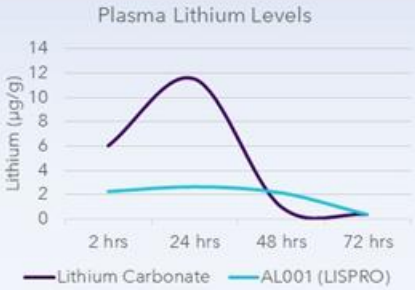
OUR SCIENCE – NON-CLINICAL

AL001 (aka LISPRO)



Lithium carbonate

- **Narrow therapeutic window** that requires **regular blood monitoring** of plasma lithium levels and blood chemistry by a clinician **to mitigate adverse events**
- **Multiple administrations** throughout the day are required to safely reach therapeutic plasma concentrations
- **Suffer** from **chronic toxicity, poor physicochemical properties** and **poor brain bioavailability**



- AL001 is a patented ionic cocrystal technology delivering a therapeutic combination of **lithium, salicylate,** and **proline.**
- AL001 exhibits **improved non-clinical pharmacokinetics** and **bioavailability** compared to the currently FDA approved lithium drugs on the market
- AL001 exhibits **improved non-clinical brain bioavailability**, without demonstrating an initial spike in lithium concentration that is associated with negative side effects of treatment
- AL001 **nonclinical brain penetration/ persistence** may translate to patients resulting in lithium dose sparing properties with enhanced overall safety and reduced or eliminated need for "TDM".

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OUR SCIENCE – NON-CLINICAL

AL001 (aka LISPRO)

The results of our preclinical studies, conducted from May 2016 to June 2017, are summarized below:

- AL001 had no effect on renal COX2 activity (Tg-Ctrl vs. AL001: $p > 0.05$), a biomarker of renal toxicity, while markedly **reducing abnormal biomarkers** associated with Alzheimer's Disease **by 50%; beta-amyloid pathology, tau phosphorylation** and **neuro-inflammation** (Tg-Ctrl vs. AL001: $p < 0.01$)(FIGS. 14A/B-15A/B).
- AL001 treatment **did not induce tissue pathological damage in the heart, kidneys, liver or lungs** by a general autopsy (Tg-Ctrl vs. AL001: $p > 0.05$). In contrast, **equimolar doses** (using a similar structure of moles but different active pharmaceutical ingredient) **of lithium carbonate enhanced renal COX2 expression** while **having little or no impact on Alzheimer's Disease pathology** (Tg-Ctrl vs. LC: $p < 0.01$).
- AL001, at the effective dose, **yielded 50% higher lithium levels** (LC vs. AL001; $p < 0.01$) **in the brain** compared with equimolar doses of lithium carbonate (AL001 vs. LC; $p < 0.05$), while producing low nontoxic steady state levels in the body.

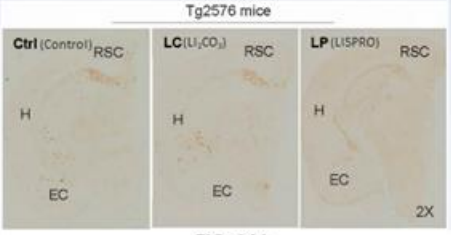

FIG. 14A

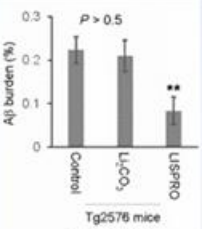

FIG. 14B

FIG. 14A & 14B: Beta Amyloid Burden

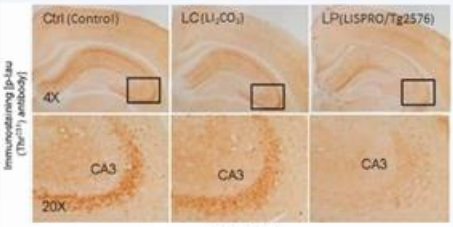

FIG. 15A

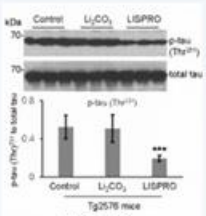

FIG. 15B

FIG. 15A & 15B: Tau Phosphorylation Burden

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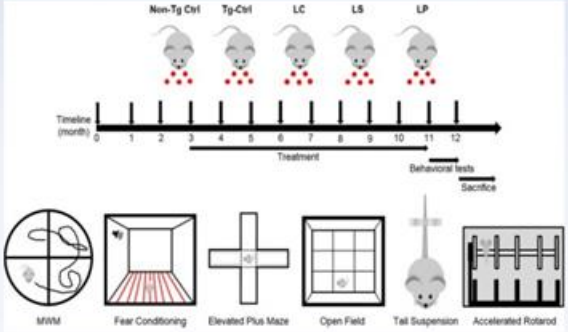
OUR SCIENCE – NON-CLINICAL

AL001 (aka LISPRO)



- Our pre-clinical studies encompassed the treatment of **28 transgenic** (or genetically modified) and **10 non-transgenic mice** with lithium carbonate and AL001.
- **Female APPSWE/PS1dE9 mice** at 4 months of age were **orally treated** with LISPRO (LP), Lithium Salicylate (LS), or Lithium Carbonate (LC) for **9 months** followed by **determination of body weight**, **growth of internal organs**, and **cognitive and non-cognitive behavior**.
- Untreated age-matched non-transgenic littermates served as Wild-Type (WT) controls.

The Results

- **No significant differences** in **body weight, brain, heart, lung, spleen, liver** or **kidney** were found between lithium treated and untreated APPSWE/PS1dE9 cohorts (Tg-Ctrl vs. AL001: $p > 0.05$).
- AL001 treatment **improved cognitive function by 50%** (Tg-Ctrl vs. AL001: $p < 0.01$), in comparison with the control group, through **behavioral tests** administered to mice with Alzheimer's Disease. The tests resulted in **50% lower escape latency** (Tg-Ctrl vs. AL001: $p < 0.01$) during the training and probe trial of the Morris water maze test and **50% longer contextual freezing time** (Tg-Ctrl vs. AL001: $p < 0.05$) during the fear conditioning test.
- AL001 treatment **reduced depression by 25%** (Tg-Ctrl vs. AL001: $p < 0.001$), as assessed by the tail suspension test, and **irritability by 50%** (Tg-Ctrl vs. AL001: $p < 0.01$), as assessed by the touch escape test.
- Continued AL001 treatment **prevented cognitive deficits**, **depression** and **irritability** and, compared to lithium carbonate treatments, was **superior** in **improving associative learning** and **memory** (LC vs. AL001: $p < 0.05$) and in **reducing irritability** (LC vs. AL001: $p < 0.01$), supporting the potential of this lithium formulation for the treatment of Alzheimer's Disease.

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OUR SCIENCE – NON-CLINICAL

Overview of ALZN002 (aka E22W)

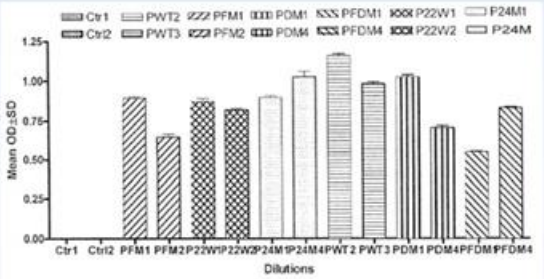

FIG. 5A

- Our goal is to develop an Alzheimer's Aß vaccine candidate that will be devoid of the problems associated with current vaccine therapies. Our studies concluded the successful vaccination of mice with adjuvant-free mutated beta amyloid peptides have significant advantages over both native beta amyloid and the use of adjuvant.
- 10 weeks old female BALB/c mice were housed in Varian standard cages including amber igloos and vaccinated when 14 weeks old.
- Differently mutated Aß 1-42 peptides were used for each group and a 1times.PBS (also containing 10% DMSO) as a control group.

The Results

- Mice vaccinated with various mutated Aß 1-42 peptides **induce antibody responses** after two inoculations, while no antibody can be detected in the control group (FIG. 5A).
- All antibodies induced by the peptide injection **bind to the same epitope**. There is no difference in recognition between the various anti-sera and peptides such that all anti-sera recognize the 1-16 epitope on all peptides.
- Demonstrate definite advantages over previous vaccination protocols, which **strongly support our Adjuvant-Free Vaccine Hypothesis.**
- The data clearly show that wild type and mutated Aß peptide administrated without adjuvant induce a **strong and long-lasting antibody response**.
- The **first use of adjuvant-free Aß** as Alzheimer's vaccine and demonstration that T-cell epitope mutation will contribute to either Th1 or Th2 response. Those peptides will have outstanding promise for the treatment of Alzheimer's Disease.

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OUR SCIENCE – NON-CLINICAL

Overview of ALZN002 (aka E22W)

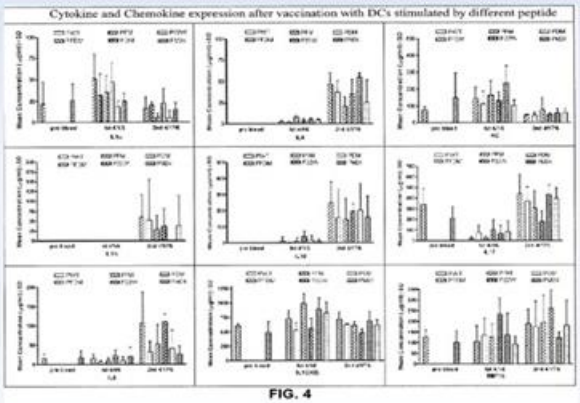

FIG. 4

- We illustrated our result by using Aß peptide pulsed Dendritic Cells ("DC") as a vaccine in Tg APP/PS1 mice.
- Aß 1-42 with different mutation were synthesized and designed as PWT (Wild-Type Abeta1-42), PFM (Aß with Flemish mutation), PDM (Aß with Dutch mutation), PFDM (Aß with both Flemish and Dutch mutation), P22W (Aß with a new mutation at amino acid 22), P24G (Aß with mutation at amino acid 24).

The Results

- There is no antibody production after two injections of DCs sensitized with Wild-Type Aß peptide (PWT). However, all other groups that received DCs sensitized with mutant Aß can **induce antibody response even with only one vaccination**. The antibody titer can reach as high as 1:16000 with only two inoculations.
- Our result indicated that the **antibody could last at least 4 months**.
- Inflammation has been considered as the very important safety issue in Alzheimer's Disease vaccine. Therefore, we have checked the antibody level to these peptide vaccinated mice. There is no difference for both Th1 and Th2 cytokine among all these groups at the same time point ($P>0.05$). It is worth noting that inflammation cytokines like IL1 and TNF.alpha. which are considered being related to **inflammation didn't increase with antibody level increase**. However, Th2 cytokine as IL4 increase with the antibody increasing (See FIG. 4).

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ALZAMEND NEURO

Overview of Alzamend Neuro's Intellectual Property (Licensed Patents)

Title of Patent	Patent Type	Therapeutic Drug	Date Filed	Date Issued	Expiration Date	Patent #
Lithium Cocrystals and an Additional Neuropsychiatric Agent for Treatment of Neuropsychiatric Disorders	Method of Use	AL001 (LISPRO)	05/21/2016	03/28/2017	05/21/2036	9,603,869
Organic Anion Lithium Ionic Cocrystal Compounds and Compositions	Composition of Matter	AL001 (LISPRO)	04/18/2014	12/12/2017	04/18/2034	9,840,521
Amyloid Beta Peptides and Methods of Use	Composition of Matter	ALZN002 (E22W)	10/12/2007	05/29/2012	02/12/2028	8,188,046

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COMPETITIVE LANDSCAPE

Overview of Top Alzheimer's Disease Drugs on the Market

Aricept		Exelon		Namenda		Leqembi	
Year Approved:	1996	Year Approved:	2000	Year Approved:	2003	Year Approved:	2023
Peak Revenue Per Year:	$3,454,000,000	Peak Revenue Per Year:	$1,067,000,000	Peak Revenue Per Year:	$2,575,000,000	Peak Revenue Per Year:	N/A
Cost Per Patient Per Year (2023):	$6,312	Cost Per Patient Per Year (2023):	$8,532	Cost Per Patient Per Year (2023):	$5,556	Cost Per Patient Per Year (2023):	$26,500
Total Revenue (2022)[A]:	$97,800,000	Total Revenue (2022)[B]:	$11,275,000	Total Revenue (2019)[C]:	$22,800,000	Total Revenue [D]:	N/A

A Aricept - Eisai Co., Ltd., Financial Results for Fiscal 2022(3/31/2023 for JPY FX) https://www.eisai.com/ir/library/settlement/pdf/e2023Q4_51.pdf
B Exelon - Knight Therapeutics 2022 Annual Report(12/30/22 for CAD FX) https://knightx.com/Investors-Content/Financial_reports/2022/Knight-AnnualReport2022-upd.pdf
C Namenda - Allergan 2019 Annual Report www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_AGN_2019.pdf
D Biogen & Eisai www.leqembi.com
Costs Per Patient: www.goodrx.com

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COMPETITIVE LANDSCAPE

Overview of Market Opportunity for AL001 and ALZN002

Patient Population	United States	Global (Including US)
MDD	21 Million[1]	280 Million[2]
PTSD	9 Million[1]	284 Million[2]
Alzheimer's Disease	6.5 Million[1]	55 Million[2]
BD	7 Million[1]	45 Million[2]
Total Patient Population	43.5 Million	664 Million

Major Depressive Disorder: 1. https://www.nimh.nih.gov/health/statistics/major-depression 2. https://www.who.int/news-room/fact-sheets/detail/depression
PTSD: 1. https://www.nimh.nih.gov/health/statistics/post-traumatic-stress-disorder.shtml 2. https://www.who.int/news/item/06-08-2013-who-releases-guidance-on-mental-health-care-after-trauma#:~:text=An%20estimated%203.6%25%20of%20the,previous%20year%2C%20the%20study%20showed
Alzheimer's: 1. https://www.alz.org/media/Documents/alzheimers-facts-and-figures.pdf 2. https://www.alzint.org/about/dementia-facts-figures/dementia-statistics/
Bipolar Disorder: 1. https://www.nimh.nih.gov/health/statistics/bipolar-disorder 2. https://www.who.int/news-room/fact-sheets/detail/mental-disorders

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ALZAMEND NEURO

Alzamend Leadership Team

Stephan Jackman

Chief Executive Officer and Director
20+ years multi-industry experience, specialized in Biotech and Pharmaceutical

Henry Nisser

Executive Vice President, General Counsel and Director
20+ years experience, U.S. securities compliance, M&A, equity/debt financings and corporate governance

Kenneth S. Cragun

Senior Vice President of Finance
30+ years SEC reporting, CFO of publicly-traded company on Nasdaq, multi-industry experience, including Biotech and Healthcare

David J. Katzoff

Chief Financial Officer
30+ years multi-industry experience, including Healthcare and Technology

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ALZAMEND NEURO

Alzamend Scientific Advisory Board

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Director, NYU Langone's Pearl I. Barlow Center for Memory Evaluation and Treatment
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Leads a Research Laboratory Continuously Funded by the National Institutes of Health for 20+ Years

Eric McDade, D.O.

Associate Director, DIAN Trials Unit & Clinical Trials Leadership, Washington University School of Medicine
Associate Professor of Neurology, Washington University School of Medicine
157+ Peer-Reviewed Journal Publications

Terri Hunter, Ph.D.

Technology Transfer and Partnerships Specialist, U.S. Department of Veterans Affairs
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Ph.D. in Medical Sciences from the University of South Florida College of Medicine

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ALZAMEND NEURO

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Chief Executive Officer and Director

20+ years multi-industry experience, specialized in Biotech and Pharmaceutical

Henry Nisser

Executive Vice President, General Counsel and Director

20+ years experience, U.S. securities compliance, M&A, equity/debt financings and corporate governance

Milton "Todd" Ault, III

Vice Chairman of Alzamend

Founder of Alzamend, Executive Chairman of Ault Alliance, the Singing Machine Company, and MTIX International

30+ years Financial Industry experience, activist investor

Lynne Fahey McGrath, Ph.D.

Regulatory Affairs and Product Development Consultant

30+ years experience, Biotech and Pharmaceuticals

M.P.H./Ph.D., Public Health from UMDNJ – Robert Wood Johnson Medical School

Jeffrey Oram

Principal at Godby Realtors

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Andrew H. Woo, M.D., Ph.D.

Practicing physician at Santa Monica Neurological Consultants, Assistant Clinical Professor of Neurology at the David Geffen School of Medicine at UCLA and Cedars-Sinai Medical Center

20+ years experience in Neurology

Mark Gustafson, C.P.A.

Chief Financial Officer of PharmaKure Limited

30+ years multi-industry experience as an active CPA, specialized in Biotech, Energy and Technology

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CONTACT US

3480 Peachtree Road NE
2nd Floor, Suite 103
Atlanta, GA 30326
+1 (844) 722-6333
Info@alzamend.com
www.alzamend.com

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