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): April 25, 2023

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: April 25, 2023

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

Alzamend Neuro, Inc.

Corporate Presentation

Alzamend®

April 2023

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, 2022 (the "2022 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 2022 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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Company Overview

NASDAQ: ALZN

Industry	Biopharmaceutical
Sector	Small Molecule / Cell Therapy
Founded	2016
IPO	June 15, 2021
Last Reported Cash	$7.4 Million (Per our 10-Q filed on March 15, 2023)
Location	Atlanta, Georgia (Corporate Headquarters)

Company Overview

Lead Drug Candidate – Ionic Cocrystal of Lithium (AL001)

Multiple Indications	Bioequivalent to Marketed Lithium Therapies	Market Opportunity
➢ AL001 is a **patented ionic cocrystal technology** delivering a therapeutic combination of **lithium**, **proline** and **salicylate** ➢ **Completed Phase I Relative Bioavailability Study** in healthy human subjects – **March 2022** ➢ **Completed Clinical Portion of a Phase IIA Multiple Ascending Dose** ("**MAD**") in patients with mild to moderate Alzheimer's Disease and Healthy Adult Subjects – **March 2023** ➢ **Anticipate Reporting Topline Data in June 2023** ➢ **Anticipate Submitting IND** ("Investigational New Drug") applications to U.S. Food and Drug Administration ("**FDA**") for **Bipolar Disorder** ("BD"), **Major Depressive Disorder** ("MDD") and **Post-Traumatic Stress Disorder** ("PTSD") in **Q4, 2023**	➢ Phase I confirmed AL001 as a **potential replacement to marketed lithium therapies** ➢ **Bioequivalence achieved at 50%** lithium content equivalent of current marketed lithium therapies ➢ May **eliminate** the need for **lithium therapeutic drug monitoring** ➢ May **eliminate the need to conduct efficacy and/or safety trials** in indications in which lithium efficacy and/or safety has been established	➢ **43.5 million** U.S. patient population ➢ **664 million** global patient population

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 ➢ Therapeutic Drug Monitoring ("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/

INTRODUCTION

Company Overview

Product Candidate	Indication	Pre-Clinical	Phase I	Phase II	Phase III	FDA Approval
AL001	• Alzheimer's Disease	→	→	• Clinical Portion of Phase IIA Multiple Ascending Dose Clinical Trial completed in March 2023 • Anticipate Reporting Topline data in June 2023		
	• Bipolar Disorder	→	→	• Anticipate Submitting IND to Initiate a Phase II Clinical Trial in Q4 2023		
	• Major Depressive Disorder	→	→	• Anticipate Submitting IND to Initiate a Phase II Clinical Trial in Q4 2023		
	• Post -Traumatic Stress Disorder	→	→	• Anticipate Submitting IND to Initiate a Phase II Clinical Trial in Q4 2023		
ALZN002	• Alzheimer's Disease	→	→	→	• Initiated Phase I/IIA Clinical Trial in March 2023	

INTRODUCTION

Company Overview

Company History

Early clinical-stage biopharmaceutical company dedicated to:

- Researching, developing and commercializing **preventions**, **treatments and cures** for neurodegenerative diseases and psychiatric disorders.
- Working on **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):

- an **ionic cocrystal of lithium** for the potential 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.

Alzheimer's Disease

Key Statistics:

7th leading cause of death in the United States

Between 2000 and 2019, deaths from heart disease have **decreased 7.3%** while deaths from Alzheimer's Disease have **increased 145%**

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

1-in-9 Americans over the age of 65 are estimated to be afflicted with 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**.

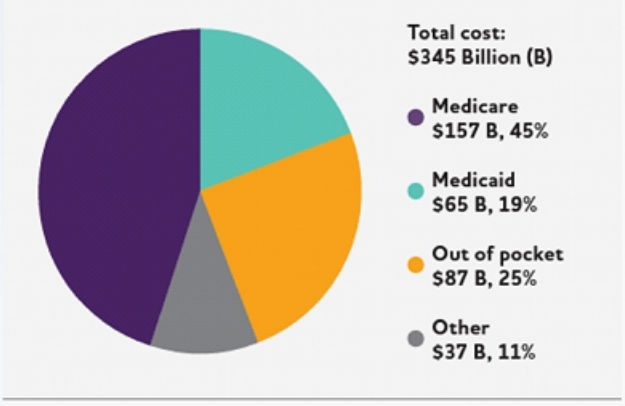
In most people with Alzheimer's Disease, symptoms first appear in their early to mid-60's. Estimates vary, but experts suggest that more than **6.5 million Americans** may have Alzheimer's Disease, considered by many as **"the most feared" disease**.

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

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

Economic Burden

Distribution of Aggregate Costs of Care by Payment Source for Americans Age 65 and Older with Alzheimer's or Other Dementias, 2023*



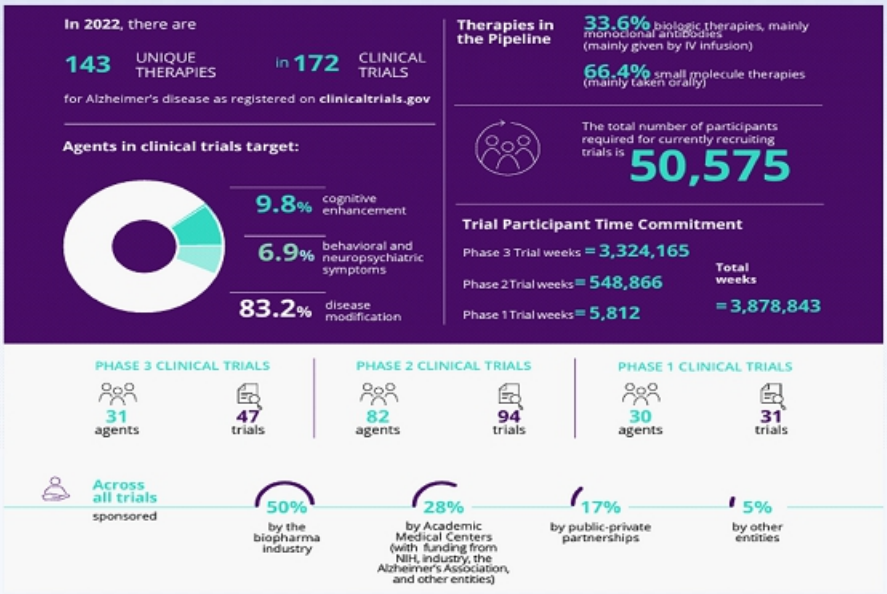
*Data are in 2023 dollars.

Important Implications

1. In 2023, the estimated **healthcare costs** for treating individuals with Alzheimer's Disease in the United States will be **$345 billion**, including $222 billion in Medicare and Medicaid payments
2. More than **11 million Americans** (family members) provide unpaid care for people with Alzheimer's Disease or other dementias - an estimated **18 billion hours of care** valued at nearly **$340 billion**
3. By 2050, **treatment for Alzheimer's Disease/dementia could rise to nearly $1 trillion per year**, most of which will be funded by Medicare & Medicaid

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

Therapeutic Landscape



https://alz-journals.onlinelibrary.wiley.com/pb-assets/hub-assets/alz-journals/infographic/TRCI-Drug-Pipeline-Infographic-2022-1651851820960.pdf

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	▪ Initiated a Phase IIA Multiple Ascending Dose Clinical Trial in May 2022 (www.clinicaltrials.gov, identifier: **NCT05363293**). ▪ Clinical Portion of Phase IIA Multiple Ascending Dose Clinical Trial completed in March 2023. ▪ Anticipate Reporting Topline data of Phase IIA Multiple Ascending Dose Clinical Trial in June 2023. ▪ Anticipate Submitting INDs for BD, MDD and PTSD in Q4 2023.
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 ▪ Difficult to manufacture and hence not easily replicated by competitors ▪ 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: **PENDING**).

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

OUR SCIENCE - CLINICAL

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**

OUR SCIENCE - CLINICAL

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 maximum tolerated dose (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 in order to:
		  • Facilitate recruitment into subsequent AL001 clinical trials
		  • Facilitate trial-adherence to completion of study requirements including treatment adherence
			• Clinical Portion of Phase IIA Multiple Ascending Dose Clinical Trial completed in March 2023 (www.clinicaltrials.gov, identifier: **NCT05363293**).
			• Anticipate Reporting Topline data of Phase IIA Multiple Ascending Dose Clinical Trial in **June 2023**.

OUR SCIENCE - CLINICAL

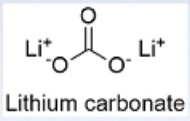
ALZN002 Phase I/IIA Trial

Study No.	Study Title	Description	Status

ALZN002- ALZ (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: **PENDING**).

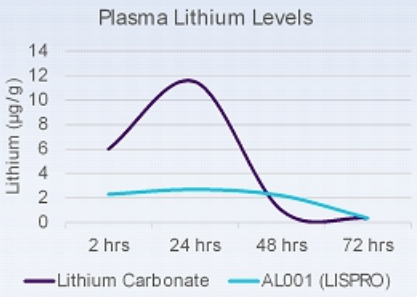
OUR SCIENCE – NON-CLINICAL

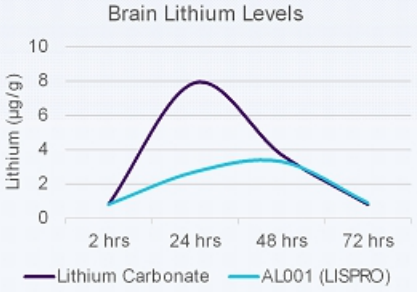
AL001 (aka LISPRO)

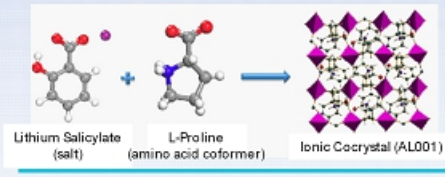


Lithium carbonate

- **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**, **proline** and **salicylate**
- 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 therapeutic drug monitoring.

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.

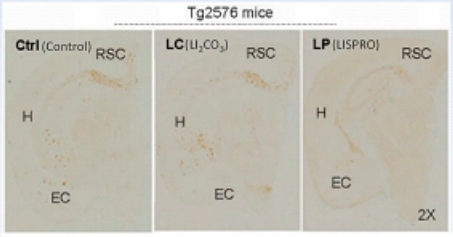


FIG. 14A

FIG. 14A & 14B: Beta Amyloid Burden

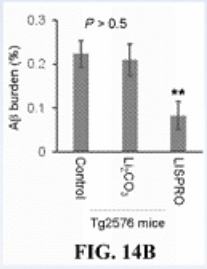


FIG. 14B

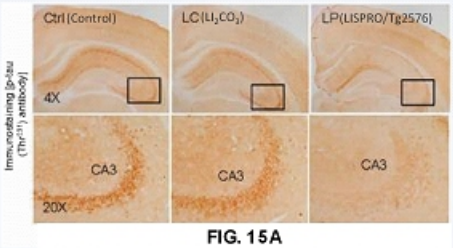


FIG. 15A

FIG. 15A & 15B: Tau Phosphorylation Burden

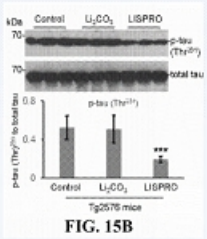
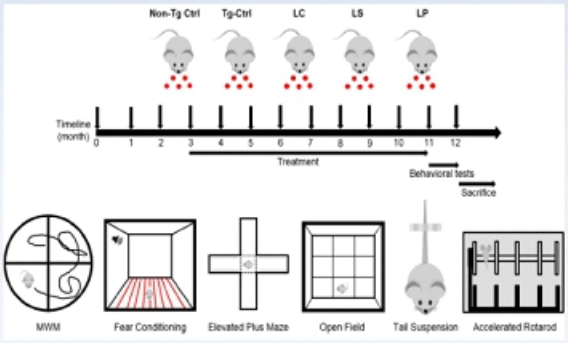


FIG. 15B

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.

OUR SCIENCE – NON-CLINICAL

Overview of ALZN002 (aka E22W)

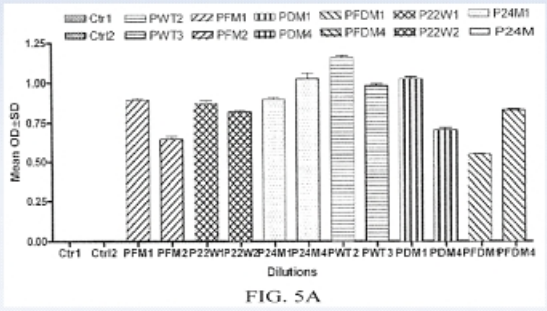


FIG. 5A

- Our goal is to develop an Alzheimer's Abeta 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 Abeta 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 Abeta 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 Abeta peptide administrated without adjuvant induce a **strong and long-lasting antibody response**.
- The **first use of adjuvant-free Abeta** 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.

OUR SCIENCE – NON-CLINICAL

Overview of ALZN002 (aka E22W)

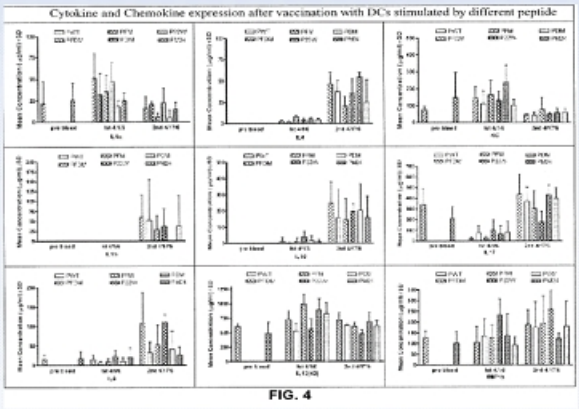


FIG. 4

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

The Results

- There is no antibody production after two injections of DCs sensitized with Wild-Type Abeta peptide (PWT). However, all other groups that received DCs sensitized with mutant Abeta 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).

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

COMPETITIVE LANDSCAPE

Overview of Top Alzheimer's Disease Drugs on the Market[1]

Aricept	
Year Approved:	1996
Peak Revenue Per Year:	$3,454,000,000
Cost Per Patient Per Year (2022):	$1,403
Total Revenue (2020)[A]:	$235,000,000

Exelon	
Year Approved:	2000
Peak Revenue Per Year:	$1,067,000,000
Cost Per Patient Per Year (2022):	$5,845
Total Revenue (2020)[B]:	$47,000,000

Namenda	
Year Approved:	2003
Peak Revenue Per Year:	$2,575,000,000
Cost Per Patient Per Year (2022):	$1,954
Total Revenue (2019)[C]:	$22,800,000

Razadyne	
Year Approved:	2004
Peak Revenue Per Year:	$428,000,000
Cost Per Patient Per Year (2022):	$1,715
Total Revenue (2019)[D]:	$156,000,000

A Aricept – Eisai Co., Ltd., Financial Results for Fiscal 2020(3/31/2021 for JPY FX) (https://www.eisai.com/ir/library/settlement/pdf/e2021Q4_51.pdf).
B Exelon – 2020 Revenues for Canada & Latin America (https://www.globenewswire.com/news-release/2021/04/23/2215925/0/en/Knight-Therapeutics-to-Acquire-Regional-Rights-to-Exelon.html).
C Namenda – Allergan 2019 Annual Report (https://www.annualreports.com/HostedData/AnnualReports/PDF/NYSE_AGN_2019.pdf)
D Razadyne(Reminyl) – Takeda FY2019 Data Book(3/31/2019 for JPY FX (https://www.takeda.com/4a24cd/siteassets/system/investors/report/quarterlyannouncements/fy2019/q/2019_q4_d_en.pdf
1 Thomson Reuters Report(top Alzheimer's drugs)- (https://www.researchgate.net/publication/274930518_Spotlight_on_Alzheimers_disease_a_Thomson_Reuters_Pharma_Matters_report).

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-ptsd 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 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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