

Corporate Presentation



**Alzamend**.

March 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 (<a href="www.sec.gov">www.sec.gov</a>). 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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## **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)	



# **Lead Drug Candidate - Ionic Cocrystal of Lithium (AL001)**

Multiple Indications	Potential Replacement to Marketed Lithium Therapies	Market Opportunity
<ul> <li>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")</li> <li>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</li> <li>Received "Study May Proceed" notification in Q3 2023 from the FDA to Initiate a Phase II Clinical Trial for treatment of Bipolar Disorder, and received "Study May Proceed" notifications for MDD and PTSD in Q4 2023</li> <li>Anticipate initiating Phase II clinical studies in Alzheimer's, BD, MDD, and PTSD patients in Q1 2024</li> </ul>	<ul> <li>Phase I and IIA Studies confirmed AL001         as a potential replacement to marketed         lithium therapies</li> <li>AL001 providing lithium at a lithium         carbonate equivalent dose of 150 mg is         bioequivalent to a marketed 300 mg         lithium carbonate capsule</li> <li>Identified a maximum tolerated dose,         providing lithium at a lithium carbonate         equivalent dose of 240-mg, designed to be         unlikely to require therapeutic drug         monitoring ("TDM")</li> <li>Safety aspects of AL001 development may         qualify for (505)(b)(2) pathway for FDA         approval</li> </ul>	<ul> <li>43.5 million U.S. patient population</li> <li>664 million global patient population</li> </ul>



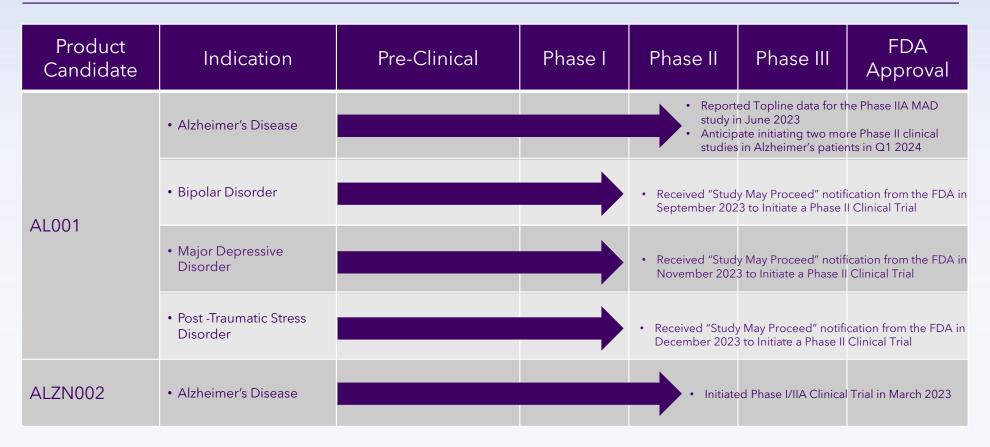
## Reference to AL001: Current Marketed Lithium - Lithium Carbonate

Usage For BD, MDD, PTSD	Challenges	Published Clinical Efficacy Studies For Alzheimer's
<ul> <li>Approved by the FDA for BD and utilized off-label for MDD, PTSD, and other neurodegenerative, neurological and neuropsychiatric disorders</li> <li>First mood stabilizer and first-line treatment for BD (Considered the gold standard treatment)</li> <li>524 clinical trials conducted for multiple indications (www.clinicaltrials.gov)</li> <li>5,444 published research articles (www.pubmed.gov)</li> </ul>	<ul> <li>Narrow         therapeutic         window</li> <li>Chronic Toxicity</li> <li>Adverse Effects</li> <li>Requires         Therapeutic Drug         Monitoring         ("TDM")</li> </ul>	<ul> <li>Forlenza, 2011<sup>(1)</sup>: Lithium significantly decrease CSF concentrations of P-tau and better performance on the cognitive subscale of the Alzheimer's Disease Assessment Scale ("ADAS-cog")         <ul> <li>(1). Forlenza, 2011: <a href="https://pubmed.ncbi.nlm.nih.gov/21525519/">https://pubmed.ncbi.nlm.nih.gov/21525519/</a></li> </ul> </li> <li>Matsunaga, 2015<sup>(2)</sup>: Lithium significantly decreased cognitive decline as compared to placebo         <ul> <li>(2). Matsunaga, 2015: <a href="https://pubmed.ncbi.nlm.nih.gov/26402004/">https://pubmed.ncbi.nlm.nih.gov/26402004/</a></li> </ul> </li> <li>Devanand, 2017<sup>(3)</sup>: 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")</li> <li>(3). Devanand, 2017: <a href="https://pubmed.ncbi.nlm.nih.gov/27819842/">https://pubmed.ncbi.nlm.nih.gov/27819842/</a></li> </ul>

### **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.

#### **OVERVIEW OF 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

Over **11 Million** Americans provide **unpaid care** for people with **Alzheimer's** or other **dementias** 

**1-in-9** Americans over the age of 65 are estimated to be afflicted with Alzheimer's Disease

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



## **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.

## Bipolar Disorder



## **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 average age of onset is **25 years old**. People ages **18 to 29 years old** had the highest rates of bipolar disorder **(4.7%)** followed by 30- to 44-year-olds **(3.5%)** 

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

## **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.

## Major Depressive Disorder



## **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

Women are almost twice as likely as men to have had depression and women who have MDD can have an increased risk of Low Bone Mass which can lead to fractures and can contribute to their risk for osteoporosis

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** 

Adults with a **depressive disorder** or symptoms have a **64% greater risk** of developing **coronary artery disease** 

## **Major Depressive Disorder:**

Major Depressive Disorder (MDD), 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.

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

## Post-Traumatic Stress Disorder



## **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.

Women are more likely to develop PTSD than men. About 8 of every 100 women (or 8%) and 4 of every 100 men (or 4%) will have PTSD at some point in their life. This is in part due to the types of traumatic events that women are more likely to experience—such as sexual assault—compared to men.

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.

## **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.

### GENERAL SCIENTIFIC OVERVIEW



## Overview of Our Science

Therapeutic Drug	Synopsis	Strength	Status
AL001	<ul> <li>Use of patented ionic cocrystal technology delivering a therapeutic combination of Lithium, Proline, and Salicylate</li> <li>Lithium as a treatment of agitation and other possible symptoms in patients with indication of Alzheimer's Disease</li> <li>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</li> </ul>	<ul> <li>Exclusive license for ionic cocrystal delivery system to treat Alzheimer's Disease</li> <li>Potential for "breakthrough therapy" designation from FDA</li> <li>Seeking a 505(b)(2) clinical trial pathway from FDA</li> <li>Formulation may importantly expand the range of therapeutic categories amenable to lithium treatments, with enhanced safety</li> <li>Has the potential of becoming the replacement for all lithium therapies on the market</li> </ul>	<ul> <li>Reported Topline data of Phase IIA         Multiple Ascending Dose Clinical Trial in         June 2023. (www.clinicaltrials.gov,         identifier: NCT05363293).</li> <li>Anticipate initiating two more Phase II         Clinical studies in Alzheimer's patients in         Q1 2024.</li> <li>Received "Study May Proceed"         notification from the FDA in Q3 2023 to         Initiate a Phase II Clinical Trial to treat         Bipolar Disorder.</li> <li>Received "Study May Proceed"         notifications from the FDA in Q4 2023 to         Initiate a Phase II Clinical Trial to treat         Major Depressive Disorder and PTSD.</li> </ul>
ALZN002	<ul> <li>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</li> </ul>	<ul> <li>Adjuvant-free therapeutic vaccine designed for the treatment and prophylactics of Alzheimer's Disease</li> <li>Potential for "breakthrough therapy" designation from FDA</li> <li>Antibody responses induced after one inoculation (Pre-Clinical) and lasted for 4 months</li> <li>Inflammation cytokines like IL1 and TNF.alpha, which are considered being related to inflammation didn't increase with antibody level increase</li> </ul>	<ul> <li>Phase I/IIA Clinical Trial Initiated in March 2023 (www.clinicaltrials.gov, identifier: NCT05834296).</li> </ul>



# AL001 Phase I Trial

Study No.	Study Title	Description	Status
AL001-ALZ01 (US)	A randomized, balanced, Phase I, singledose, 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.	<ul> <li>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.</li> <li>To characterize safety and tolerability of the tested formulations under the conditions of this study.</li> </ul>	Completed



### 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 to 150 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



## 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	<ul> <li>Primary: To evaluate the safety and tolerability of AL001 under multiple-dose, steady-state conditions in Alzheimer's subjects and healthy adult subjects</li> <li>Secondary: To characterize the maximum tolerated dose (MTD) of AL001 in subjects with mild to moderate Alzheimer's Disease and healthy adult subjects</li> <li>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:         <ul> <li>Facilitate recruitment into subsequent AL001 clinical trials</li> <li>Facilitate trial-adherence to completion of study requirements including treatment adherence</li> </ul> </li> </ul>	Reported Topline data of Phase IIA Multiple Ascending Dose Clinical Trial in June 2023. (www.clinicaltrials.gov, identifier: NCT05363293)



## Topline Results from Phase IIA Trial

## **Identify Maximum Tolerated Dose: Established**

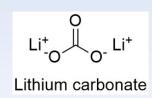
- Identified dose of lithium at a lithium carbonate equivalent dose of 240 mg 3-times a day ("TID"), is designed to be unlikely to require lithium therapeutic drug monitoring
- > No serious adverse events and no deaths were reported during the trial
- MTD is risk mitigated for the purpose of treating fragile populations, such as Alzheimer's patients
- Goal is to replace a 300 mg TID lithium carbonate dose for treatment of BPD 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



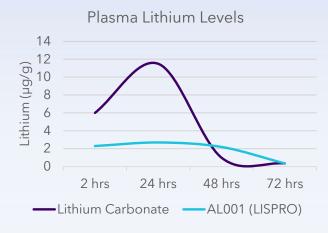
## ALZN002 Phase I/IIA Trial

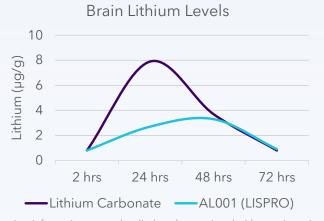
Study No.	Study Title	Description	Status
ALZN002-01(US)	A Randomized, Double-blind, Placebocontrolled, Parallel group, Phase I/IIA Study to Assess the Safety, Tolerability, and Efficacy of Autologous Amyloid Beta Mutant Peptide-Pulsed Dendritic Cells (ALZN002) in Subjects with Mild-to-Moderate Dementia of the Alzheimer's Type	<ul> <li>Primary:         <ul> <li>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</li> </ul> </li> <li>Secondary:         <ul> <li>To evaluate the immunogenicity of ALZN002 specific to generation of anti-Aβ antibodies</li> <li>To determine the effect of ALZN002 on Amyloid-Related Imaging Abnormalities (ARIA) as a putative biomarker of treatment safety</li> </ul> </li> <li>Exploratory:         <ul> <li>To assess the utility of multiple immune biomarkers as surrogates for safety and efficacy of ALZN002.</li> <li>To assess the preliminary efficacy of ALZN002 treatment on amyloid markers as observed by amyloid positron emission tomography (PET).</li> </ul> </li> </ul>	Phase I/IIA Clinical Trial Initiated in March 2023 (www.clinicaltrials.gov, identifier: NCT05834296).

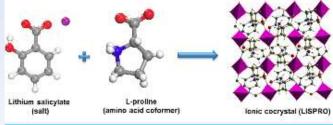
# **OUR SCIENCE - NON-CLINICAL** AL001 (aka LISPRO)



- 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 therapeutic drug monitoring.



## 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).</li>
- 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).</li>
- 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.

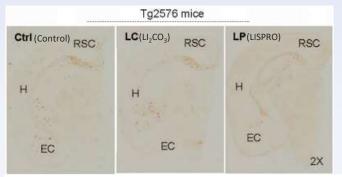
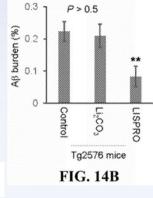


FIG. 14A FIG. 14A & 14B: Beta Amyloid Burden



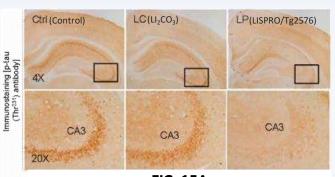
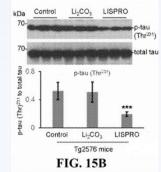
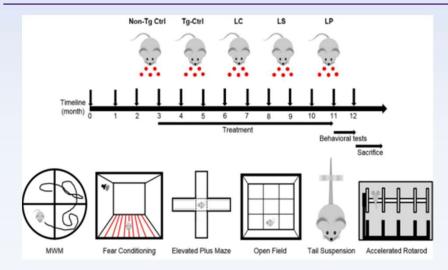


FIG. 15A FIG. 15A & 15B: Tau Phosphorylation Burden



## AL001 (aka LISPRO)



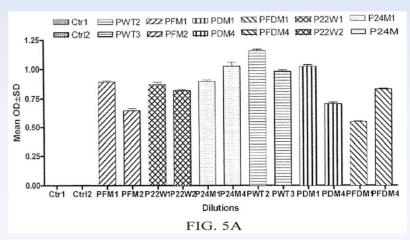
- Our pre-clinical studies encompassed the treatment of 28 transgenic (or genetically modified) and 10 non-transgenic mice with lithium carbonate and AL001.
- Female APPSWE/PS1dE9 mice at 4 months of age were orally treated with LISPRO (LP), Lithium Salicylate (LS), or Lithium Carbonate (LC) for 9 months 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 (Tq-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.</li>
- 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.</li>
- 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.</li>



## Overview of ALZN002 (aka E22W)



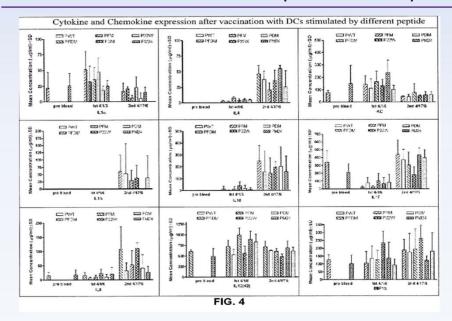
- Our goal is to develop an Alzheimer's Aß vaccine candidate that will be devoid of the problems associated with current vaccine therapies. Our studies concluded the successful vaccination of mice with adjuvant-free mutated beta amyloid peptides have significant advantages over both native beta amyloid 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 AB** 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.



## Overview of ALZN002 (aka E22W)



- 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).





# 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

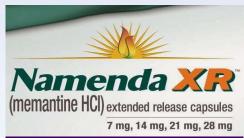
### **COMPETITIVE LANDSCAPE**



## Overview of Top Alzheimer's Disease Drugs on the Market









Aricept			
Year Approved:	1996		
Peak Revenue Per Year:	\$3,454,000,000		
Cost Per Patient Per Year (2023) :	\$6,312		
Total Revenue (2022) <sup>A</sup> :	\$97,800,000		

Exelon				
Year Approved:	2000			
Peak Revenue Per Year:	\$1,067,000,000			
Cost Per Patient Per Year (2023):	\$8,532			
Total Revenue (2022) <sup>B</sup> :	\$11,275,000			

Namenda				
Year Approved:	2003			
Peak Revenue Per Year:	\$2,575,000,000			
Cost Per Patient Per Year (2023):	\$5,556			
Total Revenue (2019) <sup>C</sup> :	\$22,800,000			

Leqembi		
Year Approved:	2023	
Peak Revenue Per Year:	N/A	
Cost Per Patient Per Year (2023):	\$26,500	
Total Revenue <sup>D</sup> :	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://knighttx.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 <u>www.leqembi.com</u> Costs Per Patient: <u>www.goodrx.com</u>

### **COMPETITIVE LANDSCAPE**



# Overview of Market Opportunity for AL001 and ALZN002

Patient Population	United States	Global (Including US)
MDD	21 Million¹	280 Million²
PTSD	9 Million¹	284 Million²
Alzheimer's Disease	6.5 Million <sup>1</sup>	55 Million <sup>2</sup>
BD	7 Million¹	45 Million <sup>2</sup>
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-traumatic-strext=An%20estimated%203.6%25%20of%20the,previous%20year%2C%20the%20study%20showed Alzheimers: 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

### **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 publiclytraded 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

### **ALZAMEND NEURO**

## Alzamend Scientific Advisory Board





Thomas M. Wisniewski, M.D.

Director, NYU Langone's Pearl I. Barlow Center for Memory Evaluation and Treatment 300+ Peer-Reviewed Medical Journal Publications (19 U.S. Patents Issued)
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 20+ years Experience, Research and Technology Transfer and Partnerships Ph.D. in Medical Sciences from the University of South Florida College of Medicine

#### **ALZAMEND NEURO**

## Alzamend Board of Directors





### William B. Horne

Chairman of Alzamend
Chief Executive Officer of Ault Alliance
25+ years Financial Industry experience, prior "Big 4" auditor and
healthcare executive



### 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



### **Stephan Jackman**

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



### **Jeffrey Oram**

Principal at Godby Realtors

25+ years multi-industry experience, Investments, Real Estate and

Technology



### **Henry Nisser**

Executive Vice President, General Counsel and Director

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



### 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



#### Milton "Todd" Ault, III

Founder of Alzamend, Executive Chairman of Ault Alliance, the Singing Machine Company, and MTIX International 30+ years Financial Industry experience, activist investor



### 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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