### UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 1-U

CURRENT REPORT PURSUANT TO REGULATION A

Date of Report: February 25, 2019 (Date of earliest event reported)

### **Alzamend Neuro, Inc.**

(Exact name of issuer as specified in its charter)

Delaware

(State or other jurisdiction of Incorporation or Organization)

**3802 Spectrum Blvd., Suite #112C, Tampa, FL 33612** (Full mailing address of principal executive offices)

(844) 722-6333 (Issuer's telephone number, including area code)

Title of each class of securities issued pursuant to Regulation A: Common Stock, par value 0.0001 per share

### ITEM 7.01 REGULATION FD DISCLOSURE.

Alzamend Neuro Inc., a Delaware corporation (the "**Company**") will participate in a series of private meetings during the week of February 25 through February 28, 2019 in the Greater New York area. The Company will have Stephan Jackman, its CEO and Milton "Todd" Ault, III, its Executive Chairman, discuss the contents of two presentations prepared by the Company (the "Corporate Presentation") at each of these meetings. The Corporate Presentation includes an overview of the Company and its management team, provides some updates on the Company's business progress and its prospective plans for 2019 and beyond, and an overview of the company's therapeutic treatments targeting Alzheimer's disease, which is attached hereto as Exhibit 99.1 and Exhibit 99.2.

The information contained in this Current Report shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the **Exchange** Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended (the **Securities Act**") or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The furnishing of the information in this Current Report on Form 1-U is not intended to, and does not, constitute a representation that such furnishing is required by Regulation FD or that the information contained in this Current Report on Form 1-U constitutes material investor information that is not otherwise publicly available.

### ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(d) Exhibits.

The following exhibits are furnished herewith:

Exhibit No.	Description
99.1	Corporate Presentation
99.2	Corporate Presentation - LiProSal

### SIGNATURES

Pursuant to the requirements of Regulation A, the issuer has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

(Exact name of issuer as specified in its charter)Alzamend Neuro Inc.

By: /s/ <u>Stephan Jackman, CEO</u> (Signature and Title)

Date: February 25, 2019



### Safe Harbor Disclaimer



This prosrialion contains forward-looking statements. All statements of historical fact are, or may be deemed to be, forward-looking statements. Such forward-looking statements in distatements of historical fact are, or may be deemed to be, forward-looking statements. Such forward-looking statements in distatements of historical fact are, or may be deemed to be, forward-looking statements. Such forward-looking statements in distatements of historical fact are, or may be deemed to be, forward-looking statements. Such forward-looking statements induce statements of historical fact are, or may be deemed to be, forward-looking statements. Such forward-looking statements, which include statements are plan, training gian, and giat or training gian, and giat or training gian, training gian, statements in training gian, training gian, statements in training gian, and giat or training gian, training gian, statements in training gian, training gian, statements, include statements in training gian, training gian, statements, include statements in training gian, training gian, statements, include statements are statements and the training gian, statements are statements in training gian, statements in training gian, statements are statements a

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- Our ability to effectively execute our business plan;
- Our ability to manage our expansion, growth and operating expenses;
- Our ability to evaluate and measure our business, prospects and performance metrics;
   Our ability to compete and succeed in a highly competitive and evolving industry;
- Our ability to respond and adapt to changes in technology and customer behavior; and
- Our ability to protect our intellectual property and to develop, maintain and enhance a strong brand.

We caution you therefore that you should not rely on any of these forward looking statements as statements of historical fact or as guarantees or assurances of future performance. All forward looking statements speak only as of the date of this presentation. We undertake no obligation to update any forward looking statements or other information contained herein.

Information regarding market and industry statistics contained in this presentation is included based on information available to us that we believe is accurate. It is generally based on academic and other publications that are not produced for purposes of resurities effortings are economic analysis. Forecasts and other forward-looking information obsined from these sources are subject to the some suaffications and the additional uncertainties accompanying any estimates of future market site, revenue and market acceptance of products and services. Except as required by U.S. federal securities laws, we have no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors that could affect those statements.

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### **Mission & Motto**



3

"To help the Alzheimer's community through the support of research and the commercialization of preventions, treatments and cures of this devastating disease."

Join Alzamend™ in "Making Alzheimer's Just a Memory"!™

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### **Our Story**



4

Alzamend Neuro<sup>™</sup> was founded in 2016 by Milton "Todd" Ault, III because of a lifelong goal to find a treatment/cure for Alzheimer's and other neurodegenerative diseases that has plagued his family for generations. His unwavering passion and commitment led him to the University of South Florida (USF) Health Byrd Alzheimer's Center and Research Institute, one the top 20 institutions in the nation for patented research and their portfolio of proprietary solutions. The Company has licensed two patented therapeutic compounds indicated for the treatment and prevention of Alzheimer's disease.

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### **Our Team** Stephan Jackman Milton "Todd" Ault, III Founder/Executive Chairman 27+ years Financial Industry experience, seasoned Wall Street CEO & activist investor Chief Executive Officer 20+ years multi-industry experience, specialized in Biotech and Pharmaceutical Kenneth S. Cragun Philip E. Mansour Board of Directors 25+ years multi-industry experience, seasoned executive, manager & coach Chief Financial 26 Officer/Treasurer/Corporate Secretary 30+ Years multi-industry experience, including Biotech and Healthcare William B. Horne Gary R. Gottlieb Director, Bus. Dev. & Administration 35+ Years multi-industry experience, including Biotech and Healthcare Board of Directors 25+ years Financial Industry experience, prior "Big 4" auditor & healthcare executive February 2019 5 Alzamend Neuro, Inc. Information cannot be disclosed or reprinted without prior written permission from Alzamend Neuro, Inc.

### **Alzamend**<sup>~~</sup>

# **Scientific Advisory Board**



### Thomas M. Wisniewski, MD

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



### Yong Fan, MD

Senior Consultant, A2Z Reg Solutions 10+ Years at the FDA/CBER/OTAT as a Quality reviewer and policy maker Knowledgeable of FDA's Expedited Programs for Serious Conditions, new policies and current thinking.

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# Scientists/Inventors



Chuanhai Cao, PhD. Inventor of CAO22W Assistant Professor, College of Medicine Neurology, University of South Florida 70+ Peer-Reviewed Journal Publications (4 U.S. Patents Issued) 30+ Years experience and a leading researcher in the field of Alzheimer's treatments.



### Roland Shytle, PhD. **Co-Inventor of LiProSal**

Associate Professor, Center of Excellence for Aging & Brain Repair, University of South Florida 30+ Peer-Reviewed Journal Publications (2 U.S. Patents Issued) 30+ Years experience and a leading researcher in Allergy, Immunology and Neurodegenerative Disease.



### Jun Tan, PhD, MD

- Co-Inventor of LiProSal Professor, College of Medicine Neurosurgery, University of South Florida 150+ Peer-Reviewed Journal Publications (14 U.S. Patents Issued)
- 30+ Years experience and a leading researcher in Metabolic Regulation and Neurodegenerative Disease.

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# Alzamend<sup>®</sup>

# Strategic Partner – TAMM Net, Inc.

Art Spaulding Founder and President, TAMM Net, Inc. 25+ years experience, including market research, reimbursement and regulatory.



Kenny Seaver, MS, RAC Regulatory Affairs, CMC Paymentister 20+ Years experience in drug metabolism, pharmacokinetics, and CMC development

February 2019









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Michael Matthews, MS, RAC Regulatory Affairs 10+ years experience preparing/reviewing technical docs required for INDs/NDAs.

# **Our Approach**



We seek out and acquire early-stage, proprietary, innovative science residing on research benchtop shelves awaiting commercialization with the patent life ticking away. There is a 20+ year backlog of scientific discoveries that may be useful in human medicine. Alzamend<sup>™</sup> finds these discoveries and fast-track develops them to bring treatments/cures to those suffering.

Alzamend<sup>™</sup> intends to secure funding by leveraging traditional channels, directed at accredited and institutional investors, and new financial regulations which permit direct marketing to the public. This approach will increase the speed, volume and breadth of capital raised while concurrently minimizing overhead costs.

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# Alzheimer's Disease

### - The sixth leading cause of death in the United States

Alzheimer's disease ("AD") is an irreversible, progressive brain disorder that slowly destroys memory and thinking skills, and eventually the ability to carry out the simplest tasks. In most people with Alzheimer's, symptoms first appear in their early to mid-60's. Estimates vary, but experts suggest that more than 5.7 million Americans may have AD, considered by many as "the most feared" disease.

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Alzheimer's has **no current cure**, but four treatments for symptoms are available today while research continues.

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# **Economic Burden – Alzheimer's**



# **Alzheimer's Therapeutic Landscape**

Phase 3 Facts 2018	Percent Change from 2017	Phase 2 Facts 2018	cent Change from 2017
Number of Drugs: 31	↓ -3%	Number of Drugs: 68	↑17%
Commercial Launch: 25 drugs could reach the market in the next five years	↓-7%	Commercial Launch: 8 drugs could reach the market in the next five years	0%
Number of Symptomatic Drugs: 12	<b>1</b> 20%	Number of Symptomatic Drugs: 13	↓-24%
Number of Disease Modifying Drugs: 19	➡-14%	Number of Disease Modifying Drugs: 55	↑ 34%
Prevention Trials: 7 drugs are in prevention trials	0%	Prevention Trials: 2 drugs are in prevention trials	0%
Mechanism of Action: 14 drugs are classified as Neurotransmission	↑ 27%	Mechanism of Action: 11 drugs are classified as Tau 12 drugs are classified as Amyloid	↑ 57% ↑ 20%

 $https://www.usagainstalzheimers.org/sites/default/files/2018\_Alzheimers\_Drug\_Pipeline\_The\_Current\_State\_OI\_Alzheimers\_Drug\_Development.pdf$ 

Based on the data above, the first of the 99 drugs is slated to reach the market in 2023. Alzamend Neuro, Inc. Information cannot be disclosed or reprinted without prior written permission from Alzamend Neuro, Inc.

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Therapeutic Drug	Synopsis	Strength	Status
LiProSal™	Use of patented lonic Courystal (ICC) technology delivering a therapeutic combination of Lithum, Proline, and Salicylate Ukhiamas a treatment of agilation and other possible symptoms in patients with indication of Alzheimer's disease. • Other potential indications: Dementia, Parkinson's Disease, ALS, Depression, B&-Pacher Olsonder, Mania, Post Traumatic Stress Disorder (PTSO), Suicidality, etc.	Exclusive license for Corrystal delivery system for AD and psychiatric indications     Eligible for "breakthrough therapy" designation from FDA Repurpose of Lithium, recognized as mood stabilizer by FDA, with the potential to receive approval of 505(b)(2) clinical trial pathway from FDA     FDA has established a separate fast-track clinical process for Cocrystal based technologies     Accelerated path for the treatment of Alzheimer's, deemed "ummet need" by the FDA	Filing pre-IND and IND in Q2 2019     Commencing human clinical trials in Q3 2019
CAO22W	<ul> <li>A patented method using a mutant peptide sensitized cell as a cell-based therapeutic vaccine that reduces beta-immfold plaque and seeks to resture the ability of the patient's immunological system to combat Alzheimer's disease.</li> <li>Also seeks to mitigate adverse reactions from a patient's immunological system experienced during pre-clinical trials including the highly publicized Elan study (AN-1972)</li> </ul>	This is the only therapeutic vaccine designed for the treatment and prophylactics of Alzheimer's     Difficult to manufacture and hence not easily replicated by competitors     Eligible for "breakthrough therapy" status via FDA     Significant support that beta-amyleid plaque is a cause in the development/progression of AD from recent Phase II Clinical Trial results released by BiogenyEsai     Accelerated path for the treatment of Alzheimer's, deemed "unnext need" by the FDA.	Completing pre-clinical studies and filing pre-INC in 02 2019     Filing IKO in 03 2019     Commencing human clinical trials in 04 2019

### **Alzamend**<sup>®</sup>

### LiProSal<sup>™</sup> (LISPRO)

- Our studies concluded that low doses of LiProSal<sup>™</sup> are safe and effective in reducing AD pathology.
- □ LiProSal<sup>™</sup> has no effect on renal COX2 activity, a biomarker of renal toxicity, while markedly reducing abnormal .beta.-amyloid pathology, tau phosphorylation and neuroinflammation (FIGS. 14-15).
- □ LiProSal<sup>™</sup> treatment did not induce tissue pathological damage in the heart, kidney, liver, and lung by a general autopsy. In contrast, equimolar doses of lithium carbonate enhanced renal COX2 expression while having little or no impact on AD pathology.
- □ LiProSal<sup>™</sup> at the effective dose yields higher lithium levels in the brain compared with equimolar doses of lithium carbonate, while producing low nontoxic steady state levels in the periphery.
- □ The improved pharmacokinetics of LiProSal<sup>™</sup> in the blood and brain explains its enhanced effectiveness and safety for treating AD compared with lithium carbonate.
- These results confirm and build upon recent studies indicating that low lithium doses can be effective in AD treatment.

February 2019



### **Alzamend**<sup>®</sup>

### LiProSal<sup>™</sup> (LISPRO)



- With the goal of improving lithium's therapeutic profile, we investigated the safety, pharmacokinetics, and therapeutic efficacy of LiProSal<sup>™</sup> (LP), compared with lithium carbonate (LC) and lithium salicylate (LS) across a host of preclinical models of AD.
- Emale APPSWE/PS1dE9 mice at 4 months of age were or ally treated with LP, LS, or 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/PSJdE9 cohorts.
   LP treatment improved cognitive function, as shown by lower escape latency during training and probe trial of the Morris water maze (MWM) test and longer contextual freezing time during the fear conditioning test.
   LP treatment also reduced depression, as assessed by tail suspension test, and irritability, as assessed by touch escape test.
   LP treatment afforded superior protection against cognitive impairment as determined by contextual fear conditioning test and irritability in comparison with LC or LS treatment.

- Onronic LP treatment prevent cognitive deficits, depression and irritability in female APPSWE/PS1dE9 mice, and is superior in improving associative learning and memory and irritability compared with lithium salioylate or carbonate treatments, supporting the potential of this lithium formulation for the treatment of AD.



February 2019

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### **CAO22W**



Our goal is to develop a safer and better Alzheimer's Abeta vaccine candidate that will be devoid of the problems associated with current vaccine therapy. Our studies concluded the successful vaccination of mice with adjuvant-free mutated Abeta peptides have significant advantages over both native Abeta 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 1.times.PBS (also containing 10% DMSO) as a control group.

### The Results:

- More 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).
- group (FIG. SA). 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 dearly show that wild type and mutated amyloid beta peptide administrated without adjuvant-free Abeta as Alzheimer's vaccines and demonstrate that T cell epitope mutation will contribute to either Th1 or Th2 response. Those peptides will have an outstanding promise for the treatment of Alzheimer's disease.



February 2019

### **Alzamend**<sup>®</sup>

### CAO22W



□ 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:

- Ite Results: There is no antbody 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 antbody titer can reach as high as 1:16000 with only two inoculators. Our result indicated that the antibody can last at least 4 months. Inflammation has been considered as the very important safety issue in AD vaccine. Therefore, we have checked the antibody level to these peptide vaccinated mice. 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 (PACOB). It is worth noting that inflammation cytokines like It1 and TNF-alpha, which are considered being related to inflammation didn't increase with antbody level increase. However, Th2 cytokine as IL4 increase with the antbody increasing (See FIG. 4).

February 2019



# Intellectual Property (Licensed Patents)

Title	Therapeutic Drug	Date Filed	Date Issued	Application/Patent #
Amyloid beta peptides and methods of use	CAO22W	10/12/2007	05/29/2012	8,188,046
Lithium Cocrystals and an Additional Neuropsychiatric Agent for Treatment of Neuropsychiatric Disorders	LiProSal™	05/21/2016	03/28/2017	9,603,869
Organic Anion Lithium Ionic Cocrystal Compounds and Compositions	LiProSal™	04/19/2013	12/12/2017	9,840,521

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# **Preliminary Budgetary Estimate**

Category	2019		2020	2021	2022	2023	5	-year Total
Phase 1 clinical trial*	\$ 5,000,000	ŝ	1,500,000	\$	\$	\$ -	\$	6,500,000
Phase 2 clinical trial*	-		7,000,000	13,000,000	7,000,000	-		27,000,000
Phase 3 clinical trial*				30,000,000	40,000,000	40,000,000		110,000,000
License fees	280,000		400,000	2,425,000	1,000,000			4,105,000
Outsourced clinical services	1,077,000		396,000	475,000	570,000	684,000		3,202,000
SG&A expenses	1,663,000		2,500,000	2,655,000	2,826,000	3,014,000		12,658,000
Total	\$ 8,020,000	\$	11,796,000	\$ 48,555,000	\$ 51,396,000	\$ 43,698,000	\$	163,465,000

\*Clinical Trial estimates vary depending on specific requirements from the FDA (Post IND).

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# **Progressed Project Timeline**

Secure CA022W IF	P Start Alzamer	Secondary Capital Initial Reg. A+ Capi Round \$1MM Round	Rai Seridge Capital Round Capital Raises and NYSE Am	
Completed Initial License Evaluation S Completed Negotlations Agreement Signed S stabilished IP Development Timeline	<ul> <li>Founders Capital Round</li> <li>Established Legal Counsel</li> <li>Engaged Auditors</li> <li>Identified and Evaluated Reg. Proposals</li> <li>Developed Brand</li> </ul>	<ul> <li>Developed PPM</li> <li>Secured Initial Investment</li> <li>Launched IOI</li> <li>Data Campaign ("Test He Waters")</li> <li>Data Campaign ("Test He Waters")</li> <li>Confidentially Filed Reg. A+ Tier II Offering with SEC</li> <li>Established Initial Regulatory Path Bear Analysis</li> <li>Launched Website and Primary Online Presence</li> <li>Developed Marketing Material Bear Test Platform</li> <li>Completed Capital Round</li> <li>Completed Capital Round</li> <li>Campaign Launched</li> </ul>	Engaged TAMM Net     Support Continuous     Move IP Forw,     Research for Current     Invest in Rese     Secure New IP     Research Funding     Research Funding     Research Funding     Research Funding     Research Funding	ard arch



# **Current Drugs – Alzheimer's**

Drug	Year Approved	Peak Revenue/Year	Cost Per Patient/Year	Total Revenue 2017
Aricept	1996	\$3,454,000,000	\$4,404	\$268,000,000
Exelon	2000	\$1,067,000,000	\$3,768	\$381,000,000
Namenda	2003	\$2,575,000,000	\$3,456	\$452,000,000
Razadyne	2004	\$428,000,000	\$3,120	\$152,000,000

Midoggi – Elesi Ga, Ud. Third Guster Francial Results (http://www.siss.com/hites/significationalis/signific

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# **Commercial Market Evaluation**



### **Potential Revenue**

Patient Population	Price per patient/yearly	10% Market Capture	20% Market Capture	30% Market Capture
6 Million	\$3,000	\$1.8 Billion	\$3.6 Billion	\$5.4 Billion
Note: See "Treating Alzheimer's	s Disease – Cost of Drugs" (https://ww	w.consumerreports.org/cro/2017	2/07/evaluating-drugs-to-treat-alz	teimer-s-disease/index.htm)
uary 2019	Alzamend Neuro, Inc. Information cannot be o	disclosed or reprinted without prior written p	ermission from Alzamend Neuro, Inc.	

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24

February 2019









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# LiProSal<sup>™</sup> Per TAMM NET

A novel drug delivery system/active pharmaceutical ingredient ionic co-crystal of lithium product (LiProSal<sup>m</sup>) that attenuates peak-to-trough concentrations via sustained-release properties yet additionally bolsters/stabilizes the ratio of brain-to-serum concentrations (enhances brain lithium exposure) could **revolutionize** the clinical utility of lithium therapy.

The blood-brain barrier, restricting access of substances into the brain, occurs along all capillaries and consists of tight junctions around the capillaries that do not exist in normal circulation. Perhaps related to this barrier and as stated earlier, it is known that lithium brain concentrations are only weakly correlated to blood lithium concentrations. Overcoming the blood-brain barrier is a daunting hurdle for pharmacologists. If brain lithium concentrations can be increased and/or be more reproducible/less variable while the total body lithium burden can be decreased, the **benefit-to-risk profile may be favorably improved for lithium treatments**. The cocrystal of lithium formulation (**LiProSal™**) may be dose-sparing, thereby lowering total body lithium exposure while maintaining efficacy, and lowering the potential for adverse events.

> "Lower dosage of LiProSal™ will produce the same if not higher efficacy, minimize side effects (if any exists) and improve the safety profile of lithium, when compared to the current therapy on the market". Hence, LiProSal™ can become the replacement for ALL lithium therapy on the market".

February 2019

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# LiProSal<sup>™</sup> Per TAMM NET

The current target by Alzamend<sup>™</sup> for an NDA exploits the enhanced absorption of ionic cocrystals of lithium (LiProSal<sup>™</sup>) into brain tissue, providing an opportunity to explore additional indications that may require relatively high brain lithium concentrations, such as for neurodegenerative disorders (Alzheimer's, Parkinson's, ALS, etc.). For these disorders, higher (or lower) brain lithium concentrations may be needed compared to those needed for mood disorders and so dose finding studies may be needed. If higher brain concentrations are needed for treatment of neurodegenerative disorders than mood disorders, systemic toxicity may only be avoidable by virtue of enhanced brain lithium distribution when using an ionic cocrystal lithium (LiProSal<sup>™</sup>) formulation, whereas traditional lithium dosage forms would have an unacceptable safety profile when achieving comparable brain lithium concentrations. If lower brain concentrations are needed for treatment of neurodegenerative disorders than mood disorders, systemic toxicity may not present when using an ionic cocrystal lithium formulation and so no therapeutic drug monitoring would be needed. An ionic cocrystal lithium (LiProSal<sup>™</sup>) formulation may importantly expand the range of therapeutic categories amenable to lithium treatments, with enhanced safety.

"Our game plan is to go after Neurodegenerative disorders (Alzheimer) because of the fast-track designation associated with the diseases. Additionally, upon approval of LiProSal" for Alzheimer's, because we will have proven its enhanced safety, physicians will be able to prescribe it off-label for psychiatric disorders".

February 2019

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# LiProSal<sup>™</sup> Regulatory Pathway

Alzamend<sup>™</sup> is pursuing a 505(b)(2) (Pages 6-8) regulatory approval pathway for LiProSal<sup>™</sup>. Currently, we are in the process of Putting together our portfolio for a Pre-IND meeting with the FDA. Upon completion, we will schedule said meeting with the FDA to review and provide guidance. Three scenarios can occur via the pre-IND meeting;

- 1. The FDA will be in favor of our information and encourage us to apply for the IND.
- 2. The FDA will require additional information, which can be to be included in our IND application.
- 3. The FDA will require additional Preclinical testing in animals.

We are working toward putting together a comprehensive package which will garner full support from the FDA with the encouragement to apply for the IND (Scenario #1). Post IND approval, we anticipate a robust Phase I Clinical Trial, adhering to all guidelines and recommendations established by the FDA, Tamm Net, and our Scientific Advisory Board. The results from Phase I testing will provide insight as to whether we will have to conduct separate Phase II and Phase III trials, skip certain steps, reduce patient count or conduct a combined Phase II/III trial. With proper funding, we anticipate a Pre-IND meeting and IND Approval in Q2, with Phase I to commence at the beginning of Q3. We anticipate Phase I to be completed within 3-6 months (pending agreement/approval by the FDA). Phase II or a potential Phase II/III combination may commence as early as Q4, 2019.

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### **Alzamend**<sup>®</sup>

# 505(b)(2) Approval Pathway

### Benefits of 505(b)(2)

505(b)(2) is particularly valuable for pharmaceutical and generics companies looking to alleviate competitive forces in their environments while still wanting to benefit from a development process that eliminates most nonclinical studies as well as extensive safety and efficacy tests.

- Relatively low risk because of previous drug approval
- Lower cost, accelerated development due to fewer studies
- May qualify for three, five or seven years of market exclusivity
- Usually faster to product commercialization and to use by patients in need.

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# 505(b)(2) Approval Pathway

### Phase I

In certain instances, the 505(b)(2) pathway enables the Phase I process to be reduced to a single study. This study, known as a Phase I bridging study, is used to compare the human pharmacokinetic profile of the proposed drug product with that of the reference product (a clinical bioequivalence study). Done properly, a bridging study allows a company to reference the established safety information for the original drug.

- The specific type of Phase I bridging study for a 505(b)(2) product depends on the nature of the dose form and the reference product. For an immediaterelease oral dosage form, for example, the Phase I study is often a fasting, single-dose, crossover bioavailability/bioequivalence (BA/BE) study in healthy human volunteers in which the new drug product is compared with the reference product using pharmacokinetic assessments. Repeat-dose studies as well as those conducted in the fed state are sometimes required as well.

  In some cases, the requirement for an *in vivo* bioequivalence study can be waived via a formal request called a biowaiver.

### Phase II

- · Certain 505(b)(2) development programs require no Phase II or Phase III studies (e.g., dosage form changes may rely on Phase I pharmacokinetic studies alone).
- In some 505(b)(2) NDAs, Phase II and Phase III studies can be combined.

### Phase III

- If a Phase III study is required for a 505(b)(2), such as when approval is sought for a product of a previously approved active ingredient, only one study is often necessary. Fewer patients may be needed for 505(b)(2) product clinical trials due to the existing large exposure information available in the public literature or in
- . the FDA's databases.

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### The Science of LiProSal™

Therapeutic Drug	Synopsis	Strength	Status
LiProSal™	<ul> <li>Use of patented Ionic Cocrystal (ICC) technology delivering a therapeutic combination of Lithium, Proline, and Sallcylate</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, Parkinson's Disease, ALS, Depression, Bi-Polar Disorder, Mania, Pest Traumatic Stress Disorder (PTSD), Suicidality, etc.</li> </ul>	Exclusive license for Cocrystal delivery system for AD and psychiatric indications     Eligible for "breakthrough therapy" designation from FDA     Repurpose of Lithium, recognized as modo stabilizer by FDA, with the potential to receive approval of 505(b)(2) clinical trial pathway from FDA     Accelerated path for the treatment of Alzheimer's because it is deemed "an unmet need" by the FDA.	Filing pre-IND and IND in Q2 2019     Commencing human clinical trials in Q3 2019

9

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### LiProSal<sup>™</sup> (LISPRO)

- □ Our studies concluded that low doses of LiProSal<sup>™</sup> are safe and effective in reducing AD pathology.
- LiProSal<sup>™</sup> has no effect on renal COX2 activity, a biomarker of renal toxicity, while markedly reducing abnormal .beta.amyloid pathology, tau phosphorylation and neuroinflammation (FIGS. 14-15).
- LiProSal<sup>™</sup> treatment did not induce tissue pathological damage in the heart, kidney, liver, and lung by a general autopsy. In contrast, equimolar doses of lithium carbonate enhanced renal COX2 expression while having little or no impact on AD pathology.
- □ LiProSal<sup>™</sup> at the effective dose yields higher lithium levels in the brain compared with equimolar doses of lithium carbonate, while producing low nontoxic steady state levels in the periphery.
- □ The improved pharmacokinetics of LiProSal™ in the blood and brain explains its enhanced effectiveness and safety for treating AD compared with lithium carbonate.
- These results confirm and build upon recent studies indicating that low lithium doses can be effective in AD treatment.

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### **Alzamend**<sup>®</sup>

### LiProSal<sup>™</sup> (LISPRO)



- □ With the goal of improving lithium's therapeutic profile, we investigated the safety, pharmacokinetics, and therapeutic efficacy of LiProSal™ (LP), compared with lithium carbonate (LC) and lithium salicylate (LS) across a host of preclinical models of AD.
- Emale APPSWE/PS1dE9 mice at 4 months of age were or ally treated with LP, LS, or 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/PSJdE9 cohorts.
   LP treatment improved cognitive function, as shown by lower escape latency during training and probe trial of the Morris water maze (MWM) test and longer contextual freezing time during the fear conditioning test.
   LP treatment also reduced depression, as assessed by tail suspension test, and irritability, as assessed by touch escape test.
   LP treatment afforded superior protection against cognitive impairment as determined by contextual fear conditioning test and irritability in comparison with LC or LS treatment.

- Onrorse LP treatment prevent cognitive definits, depression and irritability in female APPSWE/PSIdE9 mice, and is superior in improving associative learning and memory and irritability compared with lithium salicylate or carbonate treatments, supporting the potential of this lithium formulation for the treatment of AD.

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# **Commercial Market Evaluation**

### **Potential Revenue**

Patient Population	Price per patient/yearly	10% Market Capture	20% Market Capture	30% Market Capture
16.2 Million - Depression	\$2,400	\$3.9 Billion	\$7.8 Billion	\$11.7 Billion
13.0 Million – PTSD	\$4,100	\$5.3 Billion	\$10.6 Billion	\$15.9 Billion
6.0 Million - Alzheimer	\$3,000	\$1.8 Billion	\$3.6 Billion	\$5.4 Billion
5.7 Million - Bipolar Disorder	\$1,800	\$1.0 Billion	\$2.0 Billion	\$3.0 Billion
40.9 Million – Patient Popula	tion	\$12 Billion	\$24 Billion	\$36 Billion

Medication cost per year for Depression: https://dopension.informed.obsion.co/types-of-trastment/medicates Medication cost per year for Elgolar Disorder. https://www.mbi.nhm.htms/hubamed/3500000 Medication cost per year for Aldebare: https://www.mbi.nhm.elso.com/hubamed/system/motion/inset/upunten/ Medication cost per varia for PISD: https://www.markstwatch.com/hubamed/action\_amiles-2014-04-04

/h/2017/h/2017-full-w nar-maultu/gr2017\_g4\_d\_en.pdf).

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