## **UNITED STATES** SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

### FORM 1-U

### CURRENT REPORT PURSUANT TO REGULATION A

Date of Report: January 7, 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 off-site meetings during the JP Morgan Healthcare Conference being held from January 7 through January 9, 2019 in San Francisco. The Company will have Stephan Jackman, its CEO and Milton "Todd" Ault, III, its Executive Chairman, discuss the contents of a presentation 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.

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.

 99.1
 Corporate Presentation

Description

### SIGNATURES

Pursuant to the requirements of Regulation A, the issuer has duly caused this report tobe 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: January 7, 2019



## Safe Harbor Disclaimer

This preventation contain forward-loading statements. All statements of historical fast are, or may be deemed to be, forward-loading statements. Statements include statements include statements of historical fast are, or may be deemed to be, forward-loading statements. Statements include statements include statements include statements of historical fast are, or may be deemed to be, forward-loading statements. Statements include statements include statements include statements include statements include statements of historical fast are, or may be deemed to be, forward-loading statements. Statements include statem

This presentation should be read in conjunction with the audited francial statements and related notes for the fiscal year ended April 30, 2017, contained in Aleanend's", or the Company's, Annual Report on Form 1-4, as well as the condensed francial statements and related notes for the six months ended October 31, 2012, contained in the Company's Semiannual Report on Form 1-54, as field with the Securities and Exchange Commission on January 20, 2018 and January 30, 2018, respectively.

- 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 of statements 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 securities offenings or economic atalists. Forecasts and other forward-looking information obtained from these sources are subject to the some qualifications and the additional uncertainties accompanying any estimates of inture market take, revenue and market acceptance of publications. Executions and services because the subject to the some qualifications and the additional uncertainties accompanying any estimates of inture market take, revenue and market acceptance of publics and services. Execut an equiled by U.S. Ideltral securities laws, we have no obligation to update forward-looking information to reflect actual results or changes in assumptions or other factors but could related takes takes.

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research and t	zheimer's community through the support of the commercialization of preventions, treatments his devastating disease."	;
Join Alzamen	d™ in "Making Alzheimer's Just a Memory"!™	
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# **Our Story**

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 have 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 Approach**

We intend to seek 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> anticipates finding these discoveries and fast-track developing them to fulfill our mission; 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 Parcel	nt Change from 2017	Phase 2 Facts 2018	Percent Change from 2017
Number of Drugs: 31	↓ -3%	Number of Drugs: 68	<b>个</b> 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	<b>↓</b> -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\_Of\_Alzheimers\_Drug\_Development.pdf

Based on the data above, the first of the 99 drugs is slated to reach the market in 2023.

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# Our Science

Therapeutic Drug	Synopsis	Strength	Status
LiProSal™	Use of patented ionic Cocrystal (ICC) technology delivering a therapeutic combination of Lithium, Proline, and Salicylate     Uthium as a treatment of agitation and other possible symptoms in patients with indication of Alzheimer's disease     Other potential indications: Dementia, Parkinson's Disease, ALS, Depression, Bi-Polar Disorder, Mania, Post Traumatic Stress Disorder (PTSD), Suicidality, etc.	Exclusive license for Cocrystal 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(2)(b) clinical trial pathway from FDA     FDA has established a separate fast-track clinical process for Cocrystal based technologies	<ul> <li>Filing pre-IND/IND is Q1, 2019</li> <li>Commencing human clinical trials in Q2, 2019</li> </ul>
CA022W	<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> <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 of Alzheimer's     Difficult to manufacture and hence not easily replicated by competitors     Eligible for "breakthrough therapy" status via FDA     Significant support that beta-anyviold plaque is a distinct factor in the development/progression of AD from recent Phase II Clinical Trial results released by Biogen/Esai	Completing pre- clinical studies in Q2 2019     Filing pre-IND/IND in Q3, 2019     Commencing human clinical trials in Q4, 2019

#### LiProSal™(LISPRO) Tg2576 mice □ Our studies concluded that low doses of LiProSal<sup>™</sup> are safe LC(U<sub>2</sub>CO<sub>3</sub>) RSC Ctrl (Control) RSC LP(LISPRO) RSC and effective in reducing AD pathology. R □ LiProSal<sup>™</sup> has no effect on renal COX2 activity, a biomarker of renal toxicity, while markedly reducing abnormal .beta.н н H amyloid pathology, tau phosphorylation and neuroinflammation (FIGS. 14-15). <sup>100</sup> EC DH-4SI □ LiProSal<sup>™</sup> treatment did not induce tissue pathological EC EC 2X damage in the heart, kidney, liver, and lung by a general Tg2576 mice FIG. 14A autopsy. In contrast, equimolar doses of lithium carbonate enhanced renal COX2 expression while having little or no FIG. 14B impact on AD pathology. LCILICON Chi/C LP(LISPRO/Tg2576) □ 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 Allou 4X 0 the periphery. □ The improved pharmacokinetics of LiProSal<sup>™</sup> in the blood and brain explains its enhanced effectiveness and safety for CAS CA3 CA3 treating AD compared with lithium carbonate. These results confirm and build upon recent studies indicating FIG. 15A

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**FIG. 15B** 

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that low lithium doses can be effective in AD treatment. Alzement Neum, Inc. Information cannot be dis

## LiProSal<sup>™</sup> (LISPRO)

- With the goal of improving lithium's therapeutic profile, we investigated the safety, pharmacokinetics, and therapeutic efficacy of LiProSal<sup>m</sup>(LPS), compared with lithium carbonate (LC) and lithium salicylate (LS) across a host of preclinical models of AD.
- Female APPSWE/PS1dE9 mice at 4 months of age were orally treated with LPS, 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/PS1dE9 cohorts.
   LPS 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.
- □ LPS treatment also reduced depression, as assessed by tail suspension test, and irritability, as assessed by touch escape test.
- LPS treatment afforded superior protection against cognitive impairment as determined by contextual fear conditioning test and irritability in comparison with LC or LS
- Chronic LPS 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 salicylate or carbonate treatments, supporting the potential of this lithium formulation for the treatment of AD.

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## CAO22W

- Our goal is to develop a safer and better Alzheimer 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:

- 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.
- am and store recognize the 2-20 epicope over new population. Demonstrate definite advantages over previous vaccination protocols, which strongly support our Adjuvant-Free Vaccine Hypothesis.
- The data clearly show that wild type and mutated amyloid beta peptide
- administrated without adjuvant induce a strong and long lasting antibody response.

  The first use of 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.



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## CAO22W

We illustrated our result by using Abeta peptide pulsed Dendritic cells as a vaccine in Tg APP/PS1 mice.

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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.
- Contrestin Indicated that the antibuoty can last a treast a 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. 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 pathody increase IG. (A)



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# 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	s	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 I	P Start Alzameni	Secondary Capital Initial Reg. A+ Cap Round \$1.MM	tar Bridge Capital Round Private Capital \$10MM & Reg.A+ Expansion \$50MM	
<ul> <li>Completed Initial License Evaluation</li> <li>Completed Negotiations</li> <li>Agreement Signed</li> <li>Established IP Development Timeline</li> </ul>	<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>Daveloped Marketing Material and Campaign</li> <li>Launched IOI</li> <li>DTC Market Tests</li> <li>Beta Test Platform</li> <li>Comfidentially Filed Reg. 4-F Tier II</li> <li>Confidentially Filed Regulatory Path</li> <li>Performed Initial Gap Analysis</li> <li>Launched Website and Primary Online Presence</li> </ul>	Engagiat TAMM Net     Appointed Steintlic     Advisory Board     Extablished Audit and     Nomination/Governance     Committee     Addeted Cade of Ethics     B Addeted Cade of Ethics     B Addeted Cade of Ethics     Committee     Secret Additional IB     Committee     Committe	ard ; arch p
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# **Current Drugs – Alzheimer's**

Aricept	2004	\$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

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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://wv	ww.consumerreports.org/cro/201	2/07/evaluating-drugs-to-treat-alz	heimer-s-disease/index.htm)
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# **Capital Raise – Regulation A+ Tier II Process**

- Through Regulation A+, a company is afforded the opportunity to:
  Raise up to \$50 million in a 12-month period using a "public solicitation" exempt from registration under the Securities Act of 1933.
  Confidentially submit an offering statement to the SEC and "test the waters" before pursuing a small public offering.
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