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UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

**FORM 1-K**

ANNUAL REPORT

ANNUAL REPORT PURSUANT TO REGULATION A OF THE SECURITIES ACT OF 1933

For the fiscal year ended: April 30, 2018

**ALZAMEND NEURO, INC.**

(Exact name of issuer as specified in its charter)

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**Delaware**

State or other jurisdiction of  
incorporation or organization

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**2834**

(Primary Standard Industrial  
Classification Code Number)

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**81-1822909**

(I.R.S. Employer Identification No.)

**3802 Spectrum Boulevard, Suite 112C  
Tampa, Florida 33612**

(Full mailing address of principal executive offices)

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**(844) 722-6333**

(Issuer's telephone number, including area code)

**Common Stock**

(Title of each class of securities issued pursuant to Regulation A)

**Corporation Service Company  
2711 Centerville Road, Suite 400  
Wilmington, Delaware 19808**

(Name, address, including zip code, and telephone number,  
including area code, of agent for service)

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ALZAMEND NEURO, INC.

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## **Part II.**

### **STATEMENTS REGARDING FORWARD-LOOKING INFORMATION**

This Annual Report on Form 1-K contains forward-looking statements. All statements other than statements of historical fact are, or may be deemed to be, forward-looking statements. Such forward-looking statements include statements regarding, among others, (a) our expectations about possible business combinations, (b) our growth strategies, (c) our future financing plans, and (d) our anticipated needs for working capital. Forward-looking statements, which involve assumptions and describe our future plans, strategies, and expectations, are generally identifiable by use of the words “may,” “will,” “should,” “expect,” “anticipate,” “approximate,” “estimate,” “believe,” “intend,” “plan,” “budget,” “could,” “forecast,” “might,” “predict,” “shall” or “project,” or the negative of these words or other variations on these words or comparable terminology. This information may involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievements to be materially different from the future results, performance, or achievements expressed or implied by any forward-looking statements. These statements may be found in this Annual Report.

Forward-looking statements are based on our current expectations and assumptions regarding our business, potential target businesses, the economy and other future conditions. Because forward-looking statements relate to the future, by their nature, they are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict. Our actual results may differ materially from those contemplated by the forward-looking statements as a result of various factors, including, without limitation, changes in local, regional, national or global political, economic, business, competitive, market (supply and demand) and regulatory conditions and the following:

- 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 Annual Report. We undertake no obligation to update any forward-looking statements or other information contained herein.

Information regarding market and industry statistics contained in this Annual Report 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 offerings or economic analysis. Forecasts and other forward-looking information obtained from these sources are subject to the same qualifications and the additional uncertainties accompanying any estimates of future market size, 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.

#### **Item 1. Business.**

##### **DESCRIPTION OF BUSINESS**

In this Annual Report, unless the context requires otherwise, references to the “Company,” “Alzamend,” “we,” “our company” and “us” refer to Alzamend Neuro, Inc., a Delaware corporation.

##### ***Company Overview and Description of Business***

###### ***The Company***

The Company was formed on February 26, 2016 as Alzamend Neuro, Inc. under the laws of the State of Delaware. The Company was formed to acquire and commercialize patented intellectual property and know how to prevent, treat and cure the crippling and deadly Alzheimer’s disease ( “*Alzheimer’s*” or “*AD*”). The Company has developed a unique approach for combating Alzheimer’s, namely through immunotherapy. Current drugs approved by the FDA for Alzheimer’s only address symptoms and provide no benefit to the impaired immune system in Alzheimer’s.

On May 1, 2016, we obtained a royalty-bearing, exclusive worldwide license from the University of South Florida Research Foundation, Inc. (the “**University**”), to a mutant-peptide immunotherapy that is designed to be used both as a vaccine and prophylactic against Alzheimer’s. This treatment, known as CAO22W, has transitioned from early stage development to an extensive program of preclinical study and evaluation with an anticipated completion date at the end of June 2019. CAO22W will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it can provide us with any revenue. We plan to file an Investigational New Drug Application (“**IND**”) with the United States Food and Drug Administration (the “**FDA**”) with respect to CAO22W in the third quarter of 2019 and prepare to conduct a Phase 1 Clinical Trial at Emory University Alzheimer’s Disease Research Center starting in the latter half of 2019. Upon FDA approval of the IND, we plan to work with Dr. Chuanhai Cao, who is associated with the College of Chemistry, a neuroscientist at the University of South Florida Health Byrd Alzheimer’s Institute and the inventor of what we refer to as “**CAO22W**,” and Dr. Cao’s medical and biotech research team to launch our Phase 1 Clinical Trial with up to 30 human patients.

On July 2, 2018, we obtained two royalty-bearing, exclusive worldwide licenses from the Licensor to a therapy known as LiProSal<sup>TM</sup> to mitigate extreme agitation and forestall other deterioration as displayed by patients with up to moderate AD. LiProSal<sup>TM</sup> is an ionic cocrystal of lithium for the treatment of Alzheimer’s and possibly other neurodegenerative diseases. Recent evidence suggests that lithium may be efficacious for both the treatment and prevention of AD. Unlike traditional medications, which only address a single therapeutic target, lithium appears to be neuroprotective through several modes of action. For example, it exerts neuroprotective effects, in part, by increasing the brain-derived neurotrophic factor leading to restoration of learning and memory based on the results with some of the animal subjects during the preclinical studies. Another neuroprotective mechanism of lithium is attenuation of the production of inflammatory cytokines like IL-6 and nitric oxide in activated microglia. Alzamend is continuing to work with two of the inventors of this therapeutic, both at the USF Morsani College of Medicine; Jun Tan, PhD, MD, Professor at the College of Medicine Neurosurgery, Endowed Chair, College of Medicine Psychiatry and Behavioral Neurosciences and the Silver Endowed Chair in Developmental Neurobiology, Department of Psychiatry & Behavioral Medicine and Roland D. Shytle, PhD, Associate Professor, Center of Excellence for Aging & Brain Repair. Dr. Tan and Dr. Shytle with Adam J. Smith, PhD., MSBE, Michael Zaworotko, PhD., and Naga Duggirala, PhD., all formerly with the University of South Florida, have designed, synthesized and characterized this ionic cocrystal of lithium, which Alzamend has named LiProSal<sup>TM</sup>. LiProSal<sup>TM</sup> has been shown to exhibit improved pharmacokinetics compared to current FDA-approved lithium-based drugs as well as bioactive in many in vitro models of Alzheimer’s disease. LiProSal<sup>TM</sup> may prove to be a major improvement over current lithium-based treatments and may also represent a means of treating AD.

#### Technology

The patented solution that Alzamend has licensed and that it will first move to commercialization is an ionic cocrystal of lithium for the treatment of Alzheimer’s disease and a method of preparation for other pharmaceutical and industrial purposes. Lithium salts have a long history of human consumption beginning in the 1800’s. In psychiatry, they have been used to treat mania and as a prophylactic for depression since the mid-20th century. Today, lithium salts are used as a mood stabilizer for the treatment of bipolar disorder. Although the FDA has approved no medications as safe and effective treatments for suicidality, lithium has proven to be the only drug that consistently reduces suicidality in patients with neuropsychiatric disorders. Despite these effective medicinal uses, current FDA-approved lithium pharmaceuticals (lithium carbonate and lithium citrate) are limited by a narrow therapeutic window that requires regular blood monitoring of plasma lithium levels and blood chemistry by a clinician to mitigate adverse events. Because conventional lithium salts (carbonate and citrate) are eliminated relatively quickly, multiple administrations throughout the day are required to safely reach therapeutic plasma concentrations. However, existing lithium drugs such as lithium chloride and lithium carbonate suffer from chronic toxicity, poor physicochemical properties and poor brain bioavailability. Because lithium is so effective at reducing manic episodes in patients with bipolar disorder, it is still used clinically despite its narrow therapeutic index. This has led researchers to begin to look for alternatives to lithium with similar bioactivities.

The inventors from the University of South Florida have developed a new lithium cocrystal composition and method of preparation that allows for lower dosages to achieve therapeutic brain levels of lithium for psychiatric disorders, broadening lithium’s therapeutic index. The compound offers improved physicochemical properties compared to existing forms of lithium, giving it the potential to be developed as an anti-suicidal drug or for use against mood disorders. The formulation method may also be used for commercial/industrial applications such as green chemistry, engineering low density porous materials, pesticides/herbicides, explosives/propellants, and electronic materials.

Recent evidence suggests that lithium may be efficacious for both the treatment and prevention of Alzheimer's disease. Unlike traditional medications which only address a single therapeutic target, lithium appears to be neuroprotective through several modes of action. For example, it exerts neuroprotective effects, in part, by increasing a brain-derived neurotrophic factor leading to restoration of learning and memory. Another neuroprotective mechanism of lithium is attenuation of the production of inflammatory cytokines like IL-6 and nitric oxide in activated microglia. Moreover, recent clinical studies suggest that lithium treatment may reduce dementia development while preserving cognitive function and reducing biomarkers associated with AD.

This in mind, this team of inventors from the University of South Florida have designed, synthesized and characterized a new ionic cocrystal of lithium that Alzamend has named and trademarked as "LiProSal". LiProSal<sup>TM</sup> has been shown to exhibit improved pharmacokinetics compared to current FDA-approved lithium drugs as well as bioactive in many in vitro models of AD. LiProSal<sup>TM</sup> is expected to be a major improvement over current lithium-based treatments and may also constitute a means of treating Alzheimer's disease. The cocrystal technology inherently increases the therapeutic index of lithium providing a greater bioavailability and biodistribution in comparison to more traditional lithium dosage forms. Lithium has been marketed for over 35 years and human toxicology regarding lithium use has been well characterized. We plan to use the existing data available in the public domain supplanted with the knowledge that FDA has about lithium to preclude a need to conduct any further preclinical studies and to submit a pre-IND application to the FDA in early February. Upon receiving feedback from the FDA from the pre-IND, Alzamend is anticipating beginning the process of finalizing the IND application and receiving approval to begin a Phase 1 Clinical Trial with human subjects within the first half of 2019. In 2017, the FDA issued a new "FastTrack" protocol specific to cocrystal based new drug (an "**ND**A") and abbreviated new drug applications (an "**AND**A") which expedites the FDA-approval process and timeline, which will be a key component of our FDA IND application for LiProSal<sup>TM</sup>.

LiProSal<sup>TM</sup> will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it and any successors could provide us with any revenue. As a result, if we do not successfully develop, achieve regulatory approval for and commercialize LiProSal<sup>TM</sup>, our long-term business plans will not be met, and the Company may be unable to generate the revenue it has forecasted for many years, if at all. We do not anticipate that we will generate our maximum revenue for several years, or that we will achieve profitability for this therapeutic at least a few years after generating material revenue, if at all. If we are unable to generate revenue, we may not be able to pursue any expansion of the Company or acquire additional IP as we have planned, we will not become profitable with this therapeutic, and we may be unable to continue our operations.

The other patented solution that Alzamend has licensed to move to commercialization is a mutant-peptide immunotherapy that is designed to be used both as a vaccine and prophylactic against Alzheimer's, CAO22W, was developed by Dr. Cao Assistant Professor, USF Health, Assistant Professor, Morsani College of Medicine, Neurology and Associate Professor, Pharmaceutical Sciences, USF College of Pharmacy. This therapy is intended to work by stimulating the body's own immune system to prevent the formation and breakdown of beta amyloids, which build up in the brain to form a "plaque," and subsequently block the neurological brain signals, ultimately leading to the symptoms and onset of Alzheimer's. Immunotherapy is the "treatment of disease by inducing, enhancing, or suppressing an immune response." Immunotherapies that are designed to elicit or amplify an immune response are classified as activation immunotherapies, whereas immunotherapies that reduce or suppress are classified as suppression immunotherapies. We believe that strategies to strengthen the immune system in the elderly, who are most susceptible to the development of Alzheimer's, could greatly enhance the effectiveness of immune-based approaches against Alzheimer's. Our novel immune-based methodology attempts to inhibit the natural process of immunological aging by restoring the balance of immune system through immunomodulation. An exclusive license agreement with sublicensing terms (Agreement #LIC16118) was made effective on May 1, 2016, as amended on August 17, 2017 and May 7, 2018 (the "**Effective Date**") by and between the University, which is a direct support organization of the University of South Florida, and the Company.

Beta amyloid protein has been directly linked to Alzheimer's disease and the associated neurofibrillary tangles formation seen in Alzheimer's patients. Specifically, increased levels of extracellular plaques in the brain composed of amyloid beta peptide 1-42 are seen in Alzheimer's patients when compared to healthy people. Attempts have been made to help inhibit plaque formation by reducing the amount of amyloid beta peptide 1-42 through vaccines that generate an immune response to the protein. The challenge has been that though effective in reducing the amount of the protein, the inflammatory response has been such that the intended benefits are not seen. These vaccines have used an adjuvant, or helper, to generate the necessary immune response and it is believed that this adjuvant triggers the unwanted surplus inflammation. We have licensed rights to a vaccine using autologous cells that does not require an adjuvant and therefore, we believe will trigger the immune response, which should help eliminate the amyloid beta peptide 1-42 without generating the excess inflammation and therefore, have a positive clinical effect. We believe that the vaccine, in addition to dealing with plaque formation, also ameliorates the impaired immune system that is thought to be the major issue in Alzheimer's patients.

Our data have demonstrated that these mutant-peptide sensitized dendritic cells ("**DC**") can act as a vaccine to generate a durable antibody response, as well as enhance the number of CD8+ T-cells and increase the lifespan of CD8+ cells (T and DCs cells), compared to control subjects. These studies will provide a further rationale and impetus for using this novel vaccine to determine potential efficacy in human clinical trials against Alzheimer's.

CAO22W has been researched for more than ten (10) years and is currently in the midst of completing its preclinical development and has started both its pre-IND and IND application process to the FDA which is managed by TAMM Net, Inc. an experienced and highly-regarded regulatory consultancy firm. In November 2018, the Company began a toxicological preclinical 6-month study for CAO22W with Charles River Laboratories, Inc. ("**CRL**") in compliance with FDA IND requirements. Upon conclusion of this toxicological study, anticipated to occur in May 2019, we have determined that the Company will be ready to begin the process of finalizing the IND application process and move quickly forward to begin a Phase 1 Clinical Trial with human subjects. CAO22W will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it and any successors could provide us with any revenue. As a result, if we do not successfully develop, achieve regulatory approval for and commercialize CAO22W, our long-term business plans will not be met, and the Company may be unable to generate the revenue it has forecasted for CAO22W for many years, if at all. We do not anticipate that we will generate our maximum revenue for several years, or that we will achieve profitability for this therapeutic at least a few years after generating material revenue, if at all. If we are unable to generate revenue, we may not be able to pursue any expansion of the Company or acquire additional IP as we have planned, we will not become profitable with this therapeutic, and we may be unable to continue our operations.

### Market

Currently, Alzheimer's is the 6<sup>th</sup> leading cause of death in the U.S. and when extrapolated globally, the market for preventions, treatments, and cures of this crippling disease is massive. The Alzheimer's Association estimates that the cost of caring for people with Alzheimer's and other dementias will reach \$277 billion in 2018 and that by 2050, these costs may rise as high as \$1.1 trillion. Since 1990, life expectancy has increased by 6 years and the worldwide average continues to increase. With the increase in the mean age of the population in developed countries, the prevalence of deteriorating neurological diseases has also increased. According to the Alzheimer's Association, in the United States alone, 1 in 10 persons over the age of 65 have Alzheimer's disease, with more than 5.7 million Americans living with it. It is estimated that this number will increase to more than 14 million by 2050 if a cure is not found. Many Alzheimer's related associations believe the actual number of adults with AD may be as much as 5 times more or 30 million since current statistics do not take in account deaths from complications or from related diseases like pneumonia or heart attack. These death certificates only list the most immediate cause. The fastest growing age group in the United States is the "over 85" group with 1 in 3 having Alzheimer's. Women are 2½ times more likely to die from Alzheimer's than from cancer.

The rate of deaths related to Alzheimer's disease increased by 54.5 percent over 15 years, according to a new report issued on May 27, 2017 from the U.S. Centers for Disease Control and Prevention. There were 93,541 deaths related to Alzheimer's disease in 2014, a rate of 25.4 deaths per 100,000 people, up from 44,536 deaths in 1999, a rate of 16.5 deaths per 100,000 people, according to the report. The disease currently affects an estimated 5.7 million people in the U.S., but that number is expected to rise dramatically in people over the age of 65 to 13.8 million in 2050. The researchers examined death certificate data from the National Vital Statistics System to reach their findings.

Every 65 seconds, someone in the United States develops AD. Of the 10 most fatal diseases in the United States, Alzheimer's disease is the only one with no cure, no known way of deceleration and no known means of prevention. Alzamend was formed to commercialize patented intellectual property in this space, by funding it from its present state through clinical trials administered by the FDA and ultimately, if successful, potentially to the global market.

### Business Plans

Our plan of operations is currently focused on the development of both our therapeutic candidates which are at different stages in development. The Company preparing a Pre-IND application to the FDA for our first product candidate, LiProSal<sup>TM</sup>, an ionic cocrystal of lithium for the treatment of Alzheimer's disease and a method of preparation for other pharmaceutical and industrial purposes, anticipating its submission in the month of March 2019.

Our second product candidate, CAO22W, is in the midst of completing a preclinical toxicology study with CRL. Alzamend, working with its regulatory consultant, TAMM Net, has already begun the both the Pre-IND and the IND application process. At this time, the goal of these efforts is to initiate a Phase 1 Clinical Trial expected to have up to 30 human participants, contingent upon guidance from the FDA. The FDA will provide the Company with the final determination on how many participants will be required along with all other details, requirements and parameters that comprise this Phase 1 Clinical Trial.

The Company has engaged Emory University, located in Atlanta, Georgia, to develop and plan the Phase 1 Clinical Trial protocols, processes and plan. Dr. Ihab Hajjar, Neurologist at the Emory Clinic, has been selected to be the Lead Investigator for this set of preclinical activities. The Company has also retained a division of the international Swiss manufacturer, Lonza, to develop its manufacturing protocols, processes and procedures for CAO22W. Lonza is the worldwide leader in producing immunological proprietary and contracted pharma solutions. Alzamend anticipates selecting Emory University as the host for the Phase 1 Clinical Trial and to be led by Dr. Hajjar.

In November 2018, the Company adopted a Charter for its Scientific Advisory Board ("**SAB**") and is now completing the process of selecting the initial SAB members. The SAB is an important advisory group whose members will be chosen from among physicians and medical experts with various medical and clinical specializations, including extensive experience with either AD or other neurological diseases. It is from this effort, that Alzamend endeavors to gather and retain the best sources of experience and knowledge, so it may confidently rely on this group of experts to help guide it through all of its scientific and manufacturing endeavors.

The continuation of our current plan of operations to completing our IND application to progress to start the series of human clinical trials for each of our therapeutics, requires us to raise significant additional capital promptly. If we are successful in raising capital, we believe that the Company will have sufficient cash resources to fund its operations for the next twelve months or more.

Because our working capital requirements depend upon numerous factors, including the progress of our preclinical and clinical testing, timing and cost of obtaining regulatory approvals, changes in levels of resources that we devote to the development of manufacturing and marketing capabilities, competitive and technological advances, status of competitors, and our ability to establish collaborative arrangements with other organizations, we will require additional financing to fund future operations.

#### *FDA consulting and active project planning management*

The Company has retained TAMM Net, Inc., an experienced GMP, 10-year old consulting firm based in Georgia for project management; to lead, develop and manage our preclinical and clinical efforts, extending from the current status of each product candidate through the exit or commercialization of the technologies licensed by the Company. Alzamend may retain an experienced Canadian Health and European Union consulting firm to commercialize these same technologies for these geographic markets.

#### *Funding new AD research and acquisition of licenses to treat or cure AD*

Alzamend has committed to funding new research projects from Dr. Cao and his medical team for up to the next three years or more.

Alzamend obtained two royalty-bearing, exclusive worldwide licenses from the Licensor, originally called LisPro, now given the trade name of LiProSa<sup>TM</sup>, a cocrystal biologic therapy to mitigate extreme agitation and forestall further deterioration of memory as displayed by patients with up to moderate AD effective as of July 2, 2018.

Alzamend is dedicated to acquiring and supporting new research to treat or cure AD and reserves the right to evaluate and pursue each opportunity as it may arise.

#### *Establishment of advisory board, initial meetings, corporate development and initial consulting*

The Company intends to recruit top notch leaders in the Alzheimer's and business communities, who will bring their knowledge and experience to assist the Company in developing a means for the prevention, treatment and cure for Alzheimer's, to serve either on the Company's SAB or its Board of Directors (the "**Board**"). The Company established its SAB in November 2018 and is in the process of retaining its first initial members to its SAB.

## Intellectual Property and Licensing Agreements

### *Licensing Fees and ongoing project support for University of South Florida and the USF Health Byrd Alzheimer's Institute*

There are certain license fees and milestone payments required to be paid for the licensing of the CAO22W technology, pursuant to the terms of the Standard Exclusive License Agreement with Sublicensing Terms dated 05/01/2016, License #16118, (the “**CAO22W License Agreement**”) with the Licensor and the University. In addition to royalty payments of 4% on net sales of products developed from the licensed technology, the Company was required to pay a license fee of \$100,000 on June 25, 2016 and December 31, 2016 totaling \$200,000. As an additional licensing fee, the Licensor received 3,601,809 shares of the Company's Common Stock equal to five percent (5%) of the sum of the total number of issued and outstanding shares plus any securities that are convertible into or exercisable or exchangeable for shares of common stock, subject to adjustment for additional issuances until such time as the Company has received a total of \$5 million in cash in exchange for the Company's equity securities. Additionally, the Company is required to pay milestone payments on the due dates to Licensor for the license of the technology, as follows:

<b>Payment</b>	<b>Due Date</b>	<b>Event</b>
\$ 50,000	September 30, 2019	Upon IDN application filing
\$ 50,000	12 months from IND application filing date	Upon first dosing of patient in first Phase I Clinical Trial
\$ 175,000	12 months from first patient dosed in Phase I	Upon Completion of first Phase I Clinical Trial
\$ 500,000	24 months from completion of first Phase I Trial	Upon Completion of first Phase II Clinical Trial
\$ 1,000,000	12 months from completion of the first Phase II Clinical Trial	Upon first patient treated in a Phase III Clinical Trial
\$ 10,000,000	7 years from the effective date of the agreement	Upon FDA BLA Approval

None of these milestones was met as of the date of this Annual Report. If we fail to meet a milestone by its specified date, the Licensor may terminate the CAO22W License Agreement.

Licensor was also granted a preemptive right to acquire such shares of Common Stock or other equity securities that may be issued from time to time by the Company while Licensor remains the owner of any equity securities of the Company. Further, if the Company issues equity securities at a price per share that is less than the price paid by purchasers in a transaction for aggregate consideration of at least \$5,000,000 (the “**Investment Price**”), then the number of shares of Common Stock owned by Licensee shall be increased upon such issuance. The amount of the increase shall be determined by multiplying the number of shares then owned by Licensor by a fraction; the numerator of which shall be equal to the number of shares of Common Stock outstanding immediately after the issuance of additional shares of Common Stock, and the denominator of which shall be equal to the sum of (i) the number of shares of Common Stock outstanding immediately prior to the issuance of additional shares of Common Stock plus (ii) the number of shares of Common Stock which the aggregate consideration for the total number of additional shares of Common Stock so issued would purchase at the Investment Price.

Additionally, Alzamend is striving to support the ongoing work performed at the USF Health Byrd Alzheimer's Institute, a multi-disciplinary center at the University of South Florida, required for the commercialization of the CAO22W technology and further research associated with other technologies that Alzamend has and will have a first right of refusal to commercialize. Alzamend has committed to fund new research projects with Dr. Cao and his medical team over the next three years or more as a part of these efforts. In addition, Alzamend has submitted an application for \$150,000 in funds from The Florida High Tech Corridor Matching Grants Research Program. The grant is for one year and can be renewed annually with Alzamend working with the USF Senior Sponsored Research Administrator and the CRA-USF Matching Grants Program Director for the Florida High Tech Corridor to secure this grant.

There are certain license fees and milestone payments required to be paid for the licensing of the LiProSal<sup>TM</sup> technology, pursuant to the terms of the Standard Exclusive License Agreements with Sublicensing Terms, both dated July 2, 2018 (the “**LiProSal<sup>TM</sup> License Agreements**”) with the Licensor and the University. In addition, a royalty payment of 3% is required pursuant to License #18110 while License #1811 requires a royalty payment of 1.5% on net sales of products developed from the licensed technology. For the two LiProSal<sup>TM</sup> based licenses, in the aggregate, the Company is required to pay initial license fees of \$50,000 no later than July 31, 2018 and \$150,000 no later than October 31, 2018, although the Company is in discussions with the University to defer the payment due date of the initial license fees. As an additional licensing fee, the Licensor is entitled to receive that number of shares of Common Stock equal to three percent (3%) of the sum of the total number of such issued and outstanding shares. Additionally, the Company is required to pay milestone payments on the due dates to Licensor for the license of the technology, as follows:



Payment	Due Date	Event
\$ 50,000	November 1, 2019	Pre-IND meeting
\$ 65,000	6 months from IND filing date	IND application filing
\$ 190,000	12 months from IND filing date	Upon first dosing of patient in a clinical trial
\$ 500,000	12 months from first patient dosing	Upon Completion of first clinical trial
\$ 1,250,000	12 months from completion of the first Phase II clinical trial	Upon first patient treated in a Phase III Clinical Trial
\$ 10,000,000	8 years from the Effective Date of the Agreement	Upon FDA Approval

#### Our Science

Therapeutic Drug	Synopsis	Strength	Status
<b>LiProSal™</b>	<ul style="list-style-type: none"> <li>Use of patented Ionic Cocrystal (ICC) 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, Parkinson's Disease, ALS, Depression, Bi-Polar Disorder, Mania, Post Traumatic Stress Disorder (PTSD), Suicidality, etc.</li> </ul>	<ul style="list-style-type: none"> <li>Exclusive license for Cocrystal delivery system for AD and psychiatric indications</li> <li>Eligible for "breakthrough therapy" designation from FDA</li> <li>Repurpose of Lithium, recognized as mood stabilizer by FDA, with the potential to receive approval of 505(2)(b) clinical trial pathway from FDA</li> <li>FDA has established a separate fast-track clinical process for Cocrystal based technologies</li> </ul>	<ul style="list-style-type: none"> <li>Filing pre-IND/IND in Q1, 2019</li> <li>Commencing human clinical trials in Q2, 2019</li> </ul>
<b>CAO22W</b>	<ul style="list-style-type: none"> <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>	<ul style="list-style-type: none"> <li>This is the only therapeutic vaccine designed for the treatment of Alzheimer's</li> <li>Difficult to manufacture and hence not easily replicated by competitors</li> <li>Eligible for "breakthrough therapy" status via FDA</li> <li>Significant support that beta-amyloid plaque is a distinct factor in the development/progression of AD from recent Phase II Clinical Trial results released by Biogen/Esai</li> </ul>	<ul style="list-style-type: none"> <li>Completing pre-clinical studies in Q2, 2019</li> <li>Filing pre-IND/IND in Q3, 2019</li> <li>Commencing human clinical trials in Q4, 2019</li> </ul>

#### Market Opportunity

The Alzheimer's Association estimates that the cost of caring for people with Alzheimer's will reach \$277 billion dollars in 2018 and by 2050, these costs may rise as high as \$1.1 trillion. Currently, Alzheimer's is the 6th leading cause of death in the U.S. and when extrapolated globally, the market for preventions, treatments, and cures of this crippling disease is massive. Alzamend was formed to commercialize patented intellectual property in this space, by funding it from its present state through FDA Clinical Trials and ultimately, if successful, to the global market. Additionally, Alzamend is supporting ongoing research at the USF Health College of Medicine, and plans to support others with first rights of refusal on technologies for treating terminal diseases.

In an article jointly issued on April 8, 2016, Allergan and Heptares cited currently significant unmet medical needs and a heavy economic burden caused by cognitive impairment and dementia across multiple diseases, noting that currently available drugs for treating Alzheimer's disease provide limited and transient effects on cognition. They cite projections of healthcare costs, including nursing home care, associated with Alzheimer's and dementia (currently estimated to be in excess of \$640 billion for North America, Western Europe, and Asia-Pacific), that are continuing to grow based on data from the World Health Organization, Alzheimer's Disease International, the National Institute of Mental Health, and the Lewy Body Dementia Association.

This medical shortfall puts a spotlight on an urgent need for development of new therapies capable of treating the estimated more than 45 million people worldwide suffering from dementia today - 5.7 million in North America, 7.5 million in Western Europe, and 3.6 million in Asia-Pacific - a number expected to increase to more than 130 million by 2050. Alzheimer's is the most common cause of dementia, estimated to be associated with some 60 to 70 percent of cases. An additional estimated 1.4 million patients in the U.S. suffer from Lewy body dementia. The potential marketplace for a commercialized therapy or treatment would be tremendously significant with large financial support available from numerous national and international pharmaceutical companies and various governments and worldwide agencies.

These statistics were recently affirmed domestically in an article regarding the death rate and pervasiveness of Alzheimer's. The rate of deaths related to Alzheimer's disease jumped by 54.5 percent over 15 years, according to a new report issued on May 27, 2017 from the U.S. Centers for Disease Control and Prevention. There were 93,541 deaths related to Alzheimer's disease in 2014, a rate of 25.4 deaths per 100,000 people, up from 44,536 deaths in 1999, a rate of 16.5 deaths per 100,000 people, according to the report. The disease currently affects an estimated 5.3 million people in the U.S., but that number is expected to rise dramatically in people over the age of 65 to 13.8 million in 2050. The researchers examined death certificate data from the National Vital Statistics System to reach their findings.

## **Manufacturing**

We do not have any in-house manufacturing capabilities. The Company intends to outsource the manufacturing of its products to third party contractors, with special capabilities to manufacture chemical drugs and biologic drug candidates for submission and clinical testing under FDA guidelines. There are several sources of manufacturing available once a therapy or treatment can achieve Phase 2 study as identified in a publication by Pharma.org released in 2013 (<http://www.phrma.org/sites/default/files/Alzheimer's%202013.pdf>).

For CAO22W, the Company has selected the worldwide leader and authority in the manufacturing of immunological peptides, Lonza, which is a Swiss multinational, chemicals and biotechnology company, headquartered in Basel, with major facilities in Europe, North America and South Asia. Lonza was established under that name in the late 19th-century in Switzerland. The company provides product development services to the pharmaceutical and biologic industries, including organic, fine and performance chemicals, custom manufacturing of biopharmaceuticals, chemical synthesis capabilities, detection systems and services for the bioscience sector.

## **Distribution & Marketing**

We intend to develop CAO22W and LiProSal<sup>TM</sup> through successive de-risking milestones towards regulatory approval and seek marketing approval of CAO22W and LiProSal<sup>TM</sup> or effect partnering transactions with biopharmaceutical companies seeking to strategically fortify pipelines and fund the costly later-stage clinical development required to achieve successful commercialization. We do not anticipate selling products directly into the marketplace, although we may do so depending on market conditions. Our focus is to strategically effect partnering transactions which will provide distribution and marketing capabilities to sell products into the marketplace.

## **Government Regulation**

Clinical trials, the pharmaceutical approval process, and the marketing of pharmaceutical products, are intensively regulated in the U.S. and in all major foreign countries.

### Human Health Product Regulation in the U.S.

In the U.S., the FDA regulates pharmaceuticals under the Federal Food, Drug, and Cosmetic Act and related regulations. Pharmaceuticals are also subject to other federal, state, and local statutes and regulations. Failure to comply with applicable U.S. regulatory requirements at any time during the product development process, approval process or after approval may subject an applicant to administrative or judicial sanctions. These sanctions could include the imposition by the FDA of an Institutional Review Board ("IRB"), a clinical hold on trials, a refusal to approve pending applications, withdrawal of an approval, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution. Any agency or judicial enforcement action could have a material adverse effect on us.

The FDA and comparable regulatory agencies in state and local jurisdictions impose substantial requirements upon the clinical development, manufacture and marketing of pharmaceutical products. These agencies and other federal, state and local entities regulate research and development activities and the testing, manufacture, quality control, safety, effectiveness, labeling, storage, distribution, record keeping, approval, advertising and promotion of our products.

The FDA's policies may change, and additional government regulations may be enacted that could prevent or delay regulatory approval of new disease indications or label changes. We cannot predict the likelihood, nature or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or elsewhere.

#### Marketing Approval

The process required by the FDA before human health care pharmaceuticals may be marketed in the U.S. generally involves the following:

- nonclinical laboratory and, at times, animal tests;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses;
- pre-approval inspection of manufacturing facilities and clinical trial sites; and
- FDA approval of a Biologics License Application ("**BLA**"), which must occur before a drug can be marketed or sold.

We will need to successfully complete extensive clinical trials in order to be in a position to submit a BLA or NDA to the FDA. We must reach agreement with the FDA on the proposed protocols for our future clinical trials in the U.S. A separate submission to the FDA must be made for each successive clinical trial to be conducted during product development. Further, an independent IRB for each site proposing to conduct the clinical trial must review and approve the plan for any clinical trial before it commences at that site, and an informed consent must also be obtained from each study subject. Regulatory authorities, a data safety monitoring board or the sponsor, may suspend or terminate a clinical trial at any time on numerous grounds.

For purposes of BLA or NDA approval for human health products, human clinical trials are typically conducted in phases that may overlap.

- Phase I. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase II. This phase involves trials in a limited subject population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance and optimal dosage. Phase II studies may be sub-categorized to Phase IIa studies which are smaller, pilot studies to evaluate limited drug exposure and efficacy signals, and Phase IIb studies which are larger studies testing more rigorously both safety and efficacy.
- Phase III. This phase involves trials undertaken to further evaluate dosage, clinical efficacy and safety in an expanded subject population, often at geographically dispersed clinical trial sites. These trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling.

All of these trials must be conducted in accordance with Good Clinical Practice ("**GCP**") requirements in order for the data to be considered reliable for regulatory purposes.

#### New Drug and Biologics License Applications

In order to obtain approval to market a pharmaceutical in the U.S., a marketing application must be submitted to the FDA that provides data establishing to the FDA's satisfaction the safety and effectiveness of the investigational drug for the proposed indication. Each NDA or BLA submission requires a substantial user fee payment unless a waiver or exemption applies (such as with the Orphan Drug Designation discussed below). The NDA or BLA submission fee currently exceeds \$1,958,000, and the manufacturer and/or sponsor under an approved NDA or BLA are also subject to annual product and establishment user fees, currently exceeding \$98,000 per product and \$526,000 per establishment. These fees are typically increased annually. The NDA or BLA includes all relevant data available from pertinent non-clinical studies and clinical trials, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls and proposed labeling, among other things. Data can come from company-sponsored clinical trials intended to test the safety and effectiveness of a use of a product, or from a number of alternative sources, including studies initiated by investigators.

The FDA will initially review the NDA or BLA for completeness before it accepts it for filing. The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that the application is sufficiently complete to permit substantive review. After the NDA or BLA submission is accepted for filing, the FDA reviews the NDA or BLA to determine, among other things, whether the proposed product is safe and effective for its intended use, and whether the product is being manufactured in accordance with current Good Manufacturing Practices ("**cGMP**") to assure and preserve the product's identity, strength, quality and purity. The FDA may refer applications for novel drug products or drug products that present difficult questions of safety or efficacy to an advisory committee, typically a panel that includes clinicians and other experts, for review, evaluation and a recommendation as to whether the application should be approved and, if so, under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Based on pivotal Phase III trial results submitted in an NDA or BLA, upon the request of an applicant, the FDA may grant a Priority Review designation to a product, which sets the target date for FDA action on the application at six to eight months, rather than the standard ten to twelve months. The FDA can extend these reviews by three months. Priority Review is given where preliminary estimates indicate that a product, if approved, has the potential to provide a significant improvement compared to marketed products or offers a therapy where no satisfactory alternative therapy exists. Priority Review designation does not change the scientific/medical standard for approval or the quality of evidence necessary to support approval.

After the FDA completes its initial review of an NDA or BLA, it will communicate to the sponsor that the drug will either be approved, or it will issue a complete response letter to communicate that the NDA or BLA will not be approved in its current form and inform the sponsor of changes that must be made or additional clinical, nonclinical or manufacturing data that must be received before the application can be approved, with no implication regarding the ultimate approvability of the application.

Before approving an NDA or BLA, the FDA will inspect the facilities at which the product is manufactured, even if such facilities are located overseas. The FDA will not approve the product unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications.

Additionally, before approving an NDA or BLA, the FDA may inspect one or more clinical sites to assure compliance with GCP. If the FDA determines that any of the application, manufacturing process or manufacturing facilities is not acceptable, it typically will outline the deficiencies and often will request additional testing or information. This may significantly delay further review of the application. If the FDA finds that a clinical site did not conduct the clinical trial in accordance with GCP, the FDA may determine that if the data generated by the clinical site should be excluded from the primary efficacy analyses provided in the NDA or BLA. Additionally, notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval.

The testing and approval process for a drug requires substantial time, effort and financial resources, and this process may take up to several years to complete. Data obtained from clinical activities are not always conclusive and may be susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products.

The FDA may require, or companies may pursue, additional clinical trials after a product is approved. These so-called Phase IV studies may be made a condition to be satisfied for continuing drug approval. The results of Phase IV studies can confirm the effectiveness of a product candidate and can provide important safety information. In addition, the FDA now has express statutory authority to require sponsors to conduct post-market studies to specifically address safety issues identified by the agency. Any approvals that we may ultimately receive could be withdrawn if required post-marketing trials or analyses do not meet the FDA requirements, which could materially harm the commercial prospects for LiProSal<sup>TM</sup> or CAO22W.

The FDA also has authority to require a Risk Evaluation and Mitigation Strategy (“REMS”) from manufacturers to ensure that the benefits of a drug or biological product outweigh its risks. A sponsor may also voluntarily propose a REMS as part of the NDA or BLA submission. The need for a REMS is determined as part of the review of the NDA or BLA. Based on statutory standards, elements of a REMS may include “dear doctor letters,” a medication guide, more elaborate targeted educational programs, and in some cases restrictions on distribution. These elements are negotiated as part of the NDA or BLA approval, and in some cases if consensus is not obtained until after the Prescription Drug User Fee Act review cycle, the approval date may be delayed. Once adopted, REMS are subject to periodic assessment and modification.

Even if CAO22W or LiProSal<sup>TM</sup> receive regulatory approval, the approval may be limited to specific disease states, patient populations and dosages, or might contain significant limitations on use in the form of warnings, precautions or contraindications, or in the form of onerous risk management plans, restrictions on distribution, or post-marketing study requirements. Further, even after regulatory approval is obtained, later discovery of previously unknown problems with a product may result in restrictions on the product or even complete withdrawal of the product from the market. Delay in obtaining, or failure to obtain, regulatory approval for CAO22W or LiProSal<sup>TM</sup>, or obtaining approval but for significantly limited use, would harm our business. In addition, we cannot predict what adverse governmental regulations may arise from future U.S. or foreign governmental action.

#### Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, study sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these trials after completion. Disclosure of the results of these trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

#### The Drug Price Competition and Patent Term Restoration Act

The Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, requires pharmaceutical companies to divulge certain information regarding their products which has the effect of making it easier for other companies to manufacture generic drugs to compete with those products.

**Patent Term Extension.** After an NDA or BLA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug’s testing phase - the time between IND submission and NDA or BLA submission - and all of the review phase - the time between either NDA or BLA submission and approval up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the PTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which a NDA or BLA has not been submitted.

**Environmental Regulations.** The U.S. generally requires an environmental assessment, which discusses a company’s proposed action, possible alternatives to the action, and whether the further analysis of an environmental impact statement is necessary. Certain exemptions are available from the requirement to perform an environmental assessment and an environmental impact statement. Once an exemption is claimed, a company must state to the FDA that no extraordinary circumstances exist that may significantly affect the environment. We may claim an exemption, under the category for biologic products, from the requirement to provide an environmental assessment and an environmental impact statement for CAO22W or LiProSal<sup>TM</sup> and may furthermore state to the FDA that to our knowledge, no extraordinary circumstances exist that may significantly affect the environment.

## FDA Post-Approval Requirements

Following the approval of an NDA or BLA, the FDA continues to require adverse event reporting and submission of periodic reports. The FDA also may require post-marketing testing, known as Phase IV testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality control, drug manufacture, packaging, and labeling procedures must continue to conform to cGMP after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMP. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality control to maintain compliance with cGMP. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

## Patient Protection and Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act (collectively, the “**ACA**”), which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers, became law in the U.S. The ACA is a sweeping measure intended to expand health care coverage within the U.S., primarily through the imposition of health insurance mandates on employers and individuals and expansion of the Medicaid program. The ACA has significantly impacted the pharmaceutical industry. The ACA will require discounts under the Medicare drug benefit program and increased rebates on drugs covered by Medicaid. In addition, the ACA imposes an annual fee, which will increase annually, on sales by branded pharmaceutical manufacturers. At this time, the financial impact of these discounts, increased rebates and fees and the other provisions of the ACA on our business are unclear. However, the fees, discounts and other provisions of this law are expected to have a significant negative effect on the profitability of pharmaceuticals.

## **Human Health Product Regulation in the European Union**

In addition to regulations in the U.S., we may eventually be subject, either directly or through our distribution partners, to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales and distribution of our products, if approved.

Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in non-U.S. countries prior to the commencement of clinical trials or marketing of the product in those countries. Certain countries outside of the U.S. have a process that requires the submission of a clinical trial application prior to the commencement of human clinical trials. In Europe, for example, a Clinical Trial Application (“**CTA**”) must be submitted to the competent national health authority and to independent ethics committees in each country in which a company intends to conduct clinical trials. Once the CTA is approved in accordance with a country’s requirements, clinical trial development may proceed in that country.

The requirements and process governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country, even though there is already some degree of legal harmonization in the EU Member States resulting from the national implementation of underlying EU legislation. In all cases, the clinical trials are conducted in accordance with GCP and other applicable regulatory requirements.

To obtain regulatory approval of an investigational drug under EU regulatory systems, we must submit a marketing authorization application. This application is similar to the BLA in the U.S., with the exception of, among other things, country-specific document requirements. Drugs can be authorized in the EU by using (i) the centralized authorization procedure, (ii) the mutual recognition procedure, (iii) the decentralized procedure or (iv) national authorization procedures.

The European Medicines Agency (“**EMA**”) implemented the centralized procedure for the approval of human drugs to facilitate marketing authorizations that are valid throughout the EU. This procedure results in a single marketing authorization granted by the European Commission that is valid across the EU, as well as in Iceland, Liechtenstein and Norway (the “**European Community**”). The centralized procedure is compulsory for human drugs that are: (i) derived from biotechnology processes, such as genetic engineering, (ii) contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, diabetes, neurodegenerative diseases, autoimmune and other immune dysfunctions and viral diseases, (iii) officially designated orphan drugs, and (iv) advanced-therapy medicines, such as gene-therapy, somatic cell-therapy or tissue-engineered medicines. The centralized procedure may at the request of the applicant also be used for human drugs which do not fall within the above mentioned categories if the human drug (a) contains a new active substance which, on the date of entry into force of Regulation (EC) No. 726/2004, was not authorized in the European Community; or (b) the applicant shows that the medicinal product constitutes a significant therapeutic, scientific or technical innovation or that the granting of authorization in the centralized procedure is in the interests of patients at European Community level.

Under the centralized procedure in the EU, the maximum timeframe for the evaluation of a Marketing Authorization Application (“**MAA**”) by the EMA is 210 days, though the date count stops whenever the Committee for Medicinal Products for Human Use (“**CHMP**”) asks the applicant for additional written or oral information, with adoption of the actual marketing authorization by the European Commission thereafter. Accelerated evaluation might be granted by the CHMP in exceptional cases, as when a medicinal product is expected to be of a major public health interest from the point of view of therapeutic innovation, defined by three cumulative criteria: (i) the seriousness of the disease to be treated; (ii) the absence of an appropriate alternative therapeutic approach; and (iii) anticipation of exceptional high therapeutic benefit. In this circumstance, EMA ensures that the evaluation for the opinion of the CHMP is completed within 150 days and the opinion issued thereafter. We plan to submit an application for marketing authorization in the United States for LiProSal<sup>TM</sup> in the first half of 2019 and submit an application for marketing authorization in the United States for CAO22W shortly thereafter in the second half of 2019.

The Mutual Recognition Procedure (“**MRP**”), for the approval of human drugs is an alternative approach to facilitate individual national marketing authorizations within the EU. Basically, the MRP may be applied for all human drugs for which the centralized procedure is not obligatory. The MRP is applicable to the majority of conventional medicinal products and is based on the principle of recognition of an already existing national marketing authorization by one or more Member States.

The characteristic of the MRP is that the procedure builds on an already existing marketing authorization in a Member State of the EU that is used as reference in order to obtain marketing authorizations in other EU Member States. In the MRP, a marketing authorization for a drug already exists in one or more Member States of the EU and subsequently marketing authorization applications are made in other EU Member States by referring to the initial marketing authorization. The Member State in which the marketing authorization was first granted will then act as the reference Member State. The Member States where the marketing authorization is subsequently applied for act as concerned Member States.

The MRP is based on the principle of the mutual recognition by EU Member States of their respective national marketing authorizations. Based on a marketing authorization in the reference Member State, the applicant may apply for marketing authorizations in other Member States. In such case, the reference Member State shall update its existing assessment report about the drug in 90 days. After the assessment is completed, copies of the report are sent to all Member States, together with the approved summary of product characteristics, labeling and package leaflet. The concerned Member States then have 90 days to recognize the decision of the reference Member State and the summary of product characteristics, labeling and package leaflet. National marketing authorizations shall be granted within 30 days after acknowledgement of the agreement.

Should any Member State refuse to recognize the marketing authorization by the reference Member State, on the grounds of potential serious risk to public health, the issue will be referred to a coordination group. Within a timeframe of 60 days, Member States shall, within the coordination group, make all efforts to reach a consensus. If this fails, the procedure is submitted to an EMA scientific committee for arbitration. The opinion of this EMA Committee is then forwarded to the Commission, for the start of the decision-making process. As in the centralized procedure, this process entails consulting various European Commission Directorates General and the Standing Committee on Human Medicinal Products.

#### **Human Health Product Regulation in the Rest of World**

For other countries outside of the EU, such as countries in Eastern Europe or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with GCP and the other applicable regulatory requirements. If we fail to comply with applicable foreign regulatory requirements, we may be subject to, among other things, fines, suspension of clinical trials, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

#### **Other Regulatory Considerations**

##### Labeling, Marketing and Promotion

Once an NDA or BLA is approved, a product will be subject to certain post-approval requirements. For instance, the FDA closely regulates the post-approval marketing and promotion of pharmaceuticals, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities on the internet and elsewhere.

While doctors are free to prescribe any pharmaceutical approved by the FDA for any use, a company can only make claims relating to the safety and efficacy of a pharmaceutical that are consistent with the FDA approval, and is only allowed to actively market a pharmaceutical for the particular indication approved by the FDA. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or BLA or NDA/BLA supplement before the change can be implemented. A BLA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing supplements as it does in reviewing NDAs.

In addition, any claims we make for our products in advertising or promotion must be appropriately balanced with important safety information and otherwise be adequately substantiated. Failure to comply with these requirements can result in adverse publicity, warning letters, corrective advertising, injunctions and potential civil and criminal penalties. Government regulators recently have increased their scrutiny of the promotion and marketing of pharmaceuticals.

#### Anti-Kickback and False Claims Laws

In the U.S., we are subject to complex laws and regulations pertaining to health care “fraud and abuse,” including, but not limited to, The Medicare and Medicaid Patient Protection Act of 1987 (otherwise known as the federal “*Anti-Kickback Statute*”), the federal False Claims Act, state false claims acts and other state and federal laws and regulations. The Anti-Kickback Statute makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or prescription of a particular pharmaceutical, for which payment may be made under a federal health care program, such as Medicare or Medicaid.

The federal False Claims Act prohibits anyone from knowingly presenting, or causing to be presented, for payment to federal programs (including Medicare and Medicaid) claims for items or services, including pharmaceuticals, that are false or fraudulent, claims for items or services not provided as claimed, or claims for medically unnecessary items or services.

There are also an increasing number of state laws that require manufacturers to make reports to states on pricing and marketing information. Many of these laws contain ambiguities as to what is required to comply with the laws. In addition, beginning in 2013, a similar federal law requires manufacturers to track and report to the federal government certain payments made to physicians and teaching hospitals made in the previous calendar year. These laws may affect our sales, marketing, and other promotional activities by imposing administrative and compliance burdens on us. In addition, given the lack of clarity with respect to these laws and their implementation, our reporting actions could be subject to the penalty provisions of the pertinent state, and soon federal, authorities.

#### **Other Health Care Laws and Compliance Requirements**

In the U.S., our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including the Centers for Medicare and Medicaid Services (formerly the Health Care Financing Administration), other divisions of the U.S. Department of Health and Human Services (e.g., the Office of Inspector General), the U.S. Department of Justice and individual U.S. Attorney offices within the Department of Justice, and state and local governments. For example, sales, marketing and scientific/educational grant programs must comply with the anti-fraud and abuse provisions of the Social Security Act, the False Claims Act, the privacy provisions of the Health Insurance Portability and Accountability Act, and similar state laws, each as amended. Pricing and rebate programs must comply with the Medicaid rebate requirements of the Omnibus Budget Reconciliation Act of 1990 and the Veterans Health Care Act of 1992 ( “*VHCA*”), each as amended. If products are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements will apply. Under the VHCA, drug companies are required to offer certain drugs at a reduced price to a number of federal agencies including U.S. Department of Veteran Affairs and U.S. Department of Defense, the Public Health Service and certain private Public Health Service designated entities in order to participate in other federal funding programs including Medicare and Medicaid. Recent legislative changes require that discounted prices be offered for certain U.S. Department of Defense purchases for its TRICARE program via a rebate system. Participation under the VHCA requires submission of pricing data and calculation of discounts and rebates pursuant to complex statutory formulas, as well as the entry into government procurement contracts governed by the Federal Acquisition Regulations.



In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of pharmaceutical products in a state, including, in certain states, manufacturers and distributors that ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities or register their sales representatives. Other legislation has been enacted in certain states prohibiting pharmacies and other health care entities from providing certain physician prescribing data to pharmaceutical companies for use in sales and marketing and prohibiting certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

### **Diagnostics for Alzheimer's Disease**

Alzheimer's is a chronic neurodegenerative disorder affecting millions of people worldwide. It is the number one form of dementia in the world. The risk of being afflicted with Alzheimer's increases with age, with one in ten people over the age of 65 having the disease. The prevalence of the disease is approximately 5.7 million individuals in the US. Alzheimer's is also the sixth leading cause of death across all ages in the United States [AA2013: 113], and its prevalence is expected to quadruple by 2050. On the other hand, the incidence (or rate at which new cases of disease develop) is age dependent with approximately 53 new cases per 1,000 people age 65 to 74, 170 new cases per 1,000 people age 75 to 84, and 231 new cases per 1,000 people age 85 and older, with 454,000 new cases occurring in 2010 [Alzheimer's Association, 2013 Alzheimer's Disease Facts and Figures, Alzheimer's & Dementia, Volume 9, Issue 2]. It is estimated that the cost of caring for people with Alzheimer's and other dementias will increase from an estimated \$277 billion in 2018 to a projected \$1.1 trillion per year by 2050 with Medicare and Medicaid covering approximately 70% of such costs. Over 16 million Americans provide unpaid care for people with Alzheimer's disease or other dementias. It is estimated that in 2017 caregivers to people with Alzheimer's provided 18.4 billion hours of care valued at \$232 billion.

The cause and progression of Alzheimer's disease are not well understood. As of 2015, more than 1,200 clinical trials have been or are being conducted to find ways to treat the disease, but it is unknown if any of the tested treatments will work.

According to the Alzheimer's Foundation of America, it is widely accepted that with the increasing trend towards a longer lifespan coupled with the baby-boomer population approaching retirement, the incidence of Alzheimer's is likely to double in the next 20 years. The exponential increase in the expected number of patients presenting with Alzheimer's not only represents a major area of unmet medical need, but it also represents a significant market opportunity for diagnostics for this disease. Alzheimer's biomarker sales in 2011 were reported at \$1.5 billion but are expected have doubled in 2018 to over \$3 billion. (BCC research 2013, Advances in biomarker and monitoring diagnostics: Great markets, not so great health effects by Bjørn Hofmann PhD and H. Gilbert Welch MD, MPH, 2017).

Current clinical research focuses on the early phases of the disease. However, no accurate and convenient tools are available today for pre-dementia diagnosis of Alzheimer's to support these efforts. Currently Alzheimer's is diagnosed as a clinical entity using a process that combines cognition assessments with imaging- and spinal-fluid ("CSF") tests. This diagnostic procedure may last for several months to a year and is usually initiated late in the disease development.

Several companies are focusing on blood as a test material. Typically, these companies employ a multi-assay strategy (multiple RNAs or proteins) combined with advanced statistical tools/algorithms to develop disease-specific diagnostic models.

### **Intellectual Property**

We are able to protect our technology from unauthorized use by third parties only to the extent that it is covered by valid and enforceable patents or is effectively maintained as a trade secret or is protected by confidentiality agreements. Accordingly, patents or other proprietary rights are an essential element of our business. Currently, the Company does not own a patent although it does possess a license for an immunotherapy technology and two licenses for a lithium salt and proline cocrystal technology from the University of South Florida Research Foundation, Inc.

Patents extend for varying periods according to the date of patent filing or grant and the legal term of patents in the various countries where patent protection is obtained. The actual protection afforded by a patent, which can vary from country to country, depends on the type of patent, the scope of its coverage and the availability of legal remedies in the country.

While trade secret protection is an essential element of our business and we take security measures to protect our proprietary information and trade secrets, we cannot give assurance that our unpatented proprietary technology will afford us significant commercial protection. We seek to protect our trade secrets by entering into confidentiality agreements with third parties, employees and consultants. Our employees and consultants also sign agreements requiring that they assign to the Company their interests in intellectual property arising from their work for us. All employees sign an agreement not to engage in any conflicting employment or activity during their employment and not to disclose or misuse confidential information. However, it is possible that these agreements may be breached or invalidated, and if so, there may not be an adequate corrective remedy available. Accordingly, we cannot ensure that employees, consultants or third parties will not breach the confidentiality provisions in our contracts, infringe or misappropriate our trade secrets and other proprietary rights or that measures we take to protect our proprietary rights will be adequate.

In the future, third parties may file claims asserting that our technologies or products infringe on their intellectual property. We cannot predict whether third parties will assert such claims against us or against the licensors of technology licensed to us, or whether those claims will harm our business. If we are forced to defend ourselves against such claims, whether they are with or without merit and whether they are resolved in favor of, or against, our licensors or ourselves, we may face costly litigation and the diversion of our management's attention and resources. As a result of such disputes, we may have to develop costly non-infringing technology or enter into licensing agreements. These agreements, if necessary, may be unavailable on terms acceptable to us, or at all.

Alzamend currently possesses 4 service trademarks with the U.S. PTO that include its corporate name, Alzamend Neuro<sup>TM</sup>; two for its corporate slogan and one for the trade name, LiProSal<sup>TM</sup>.

## Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we have some, albeit limited, development experience and scientific knowledge, we will face competition from both large and small pharmaceutical and biotechnology companies, including specialty pharmaceutical companies and generic drug companies, as well as academic institutions, government agencies and research institutions, among others.

Our competition will be determined in part by the potential indications for which our products are developed and ultimately approved by regulatory authorities. It is likely that the timing of market introductions of some of our potential products or our competitors' products will be an important competitive factor. Accordingly, the speed with which we can develop our products, conduct preclinical studies and clinical trials to obtain approval and manufacture or obtain supplies of commercial quantities of any approved products should also be important competitive factors. We expect that competition among products approved for sale will be based on additional factors, such as product efficacy, safety, reliability, availability, price and patent position.

## Alzheimer's Therapeutic Landscape

Phase 3 Facts 2018		Phase 2 Facts 2018	
	Percent Change from 2017		Percent 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	↑ 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%

## Current Drugs for Alzheimer's Disease

Drug	Year Approved	Peak Revenue/Year	Cost Per Patient/Year	Total Revenue 2017
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

- Aricept – Eisai Co., Ltd. Third Quarter Financial Results ([https://www.eisai.com/ir/library/settlement/pdf/e2018Q3\\_52.pdf](https://www.eisai.com/ir/library/settlement/pdf/e2018Q3_52.pdf)).
- Exelon – Novartis Pharmaceutical Co. Q4/FY 2017 Financial Report (<https://www.novartis.com/sites/www.novartis.com/files/2018-01-interim-financial-report-en.pdf>).
- Namenda – Allergan Q4/FY 2017 Financial Report (<https://www.prnewswire.com/news-releases/allergan-reports-solid-finish-to-2017-with-12-increase-in-fourth-quarter-gaap-net-revenues-to-43-billion-300593801.html>).
- Razadyne – Takeda FY2017 Data Book ([https://www.takeda.com/siteassets/system/investors/report/quarterlyannouncements/fy2017/fy2017-full-year-results/qr2017\\_q4\\_d\\_en.pdf](https://www.takeda.com/siteassets/system/investors/report/quarterlyannouncements/fy2017/fy2017-full-year-results/qr2017_q4_d_en.pdf)).
- Thomson Reuters Report - ([https://www.researchgate.net/publication/274930518\\_Spotlight\\_on\\_Alzheimers\\_disease\\_a\\_Thomson\\_Reuters\\_Pharma\\_Matters\\_report](https://www.researchgate.net/publication/274930518_Spotlight_on_Alzheimers_disease_a_Thomson_Reuters_Pharma_Matters_report)).

## Diagnostics for Alzheimer's Disease

### Cerebrospinal Fluid (CSF)

CSF samples and protein assays of particular analytes remain today the best tools in the diagnosis of Alzheimer's disease and encephalitis. The procedure involves a lumbar puncture - the insertion of a hollow cannula or needle into the lower spinal column in order to collect 5-10 ml of blood free CSF. Until recently there have not been any in vitro diagnostic quality assays available to replace the lumbar puncture diagnostic procedure and there may not be until Saladax/Ortho Clinical Diagnostics or Roche Diagnostics release publicly their report CSF Ab42 and CSF Tau assays.

### Positron Emission Tomography (PET)

PET requires large, multi-million-dollar cameras which collect the radioactive decay of minute quantities of hot radioactive tracers injected into the blood stream. The tracers emit correlated photo pairs which indicate where the tracer is staining tissue in vivo. FDG-PET is an FDA-approved tracer which measures glucose metabolism and has been successfully used to image brain energy consumption. More recently Amyvid from Avid Radiopharmaceuticals, now Lilly Diagnostics, received FDA approval as an in vivo radiotracer to label the amyloid plaques of the brain. These studies typically cost \$3,000-\$5,000 per imaging session per patient and require patients travel to a facility with a PET facility rather than receive a diagnostic test in their clinician's office.

### Magneto encephalography (MEG)

MEG instruments, which are both physically large and costly to facilities wishing to purchase them, employ advanced superconducting magnets operating in near absolute zero temperature to measure minute brain currents. They are scarcely available in the US and Japan, let alone any other country in the world. They are primarily used for research and will likely never become commonplace in clinical practice due to their size and cost.

### Magnetic Resonance Imaging (MRI)

MRI instruments are able to measure the gross anatomy of the brain within the skull with resolution approaching 100 microns in a standard 1.5T clinical MRI. Although they are costly and accessible only at an imaging center (in patient or outpatient), they are standard of care to ensure that there is no gross brain tumor or evidence of white matter infarct, typical after sub-clinical or mini-strokes have occurred. In one costly modality, functional MRI is conducted whereby a patient is given tasks to complete while they are lying in an MRI brain scanner and asked to participate in task-based maneuvers to understand which anatomical structures are active during which dynamic task. These diagnostic studies are costly and difficult to implement with satisfactory results due to the distractions of motion artifacts and noise. In routine clinical practice, they are not commonly conducted.

### Cognition

There are many companies creating computerized cognitive assessments of a human subject from a neuropsychological perspective. Many of these are considered reliable and easily administered in a clinician's office. Some of the cognitive assessment tools in the market today are the CogState battery of tasks, the CNS Vital Signs, the ImPACT test and the CANTAB battery. However, these cognition assessment tools have limitations on their ability to accurately and objectively measure brain function.

### **Employees**

As of the date of this Annual Report, the Company has two full-time and one part-time employee.

### **Corporate Information**

Our mailing address is Alzamend Neuro, Inc., 3802 Spectrum Blvd., Suite #112C, Tampa, FL 33612 and our telephone number is (844) 722-6333. Our website address is [www.alzamend.com](http://www.alzamend.com) and the [www.TheAlzamendStory.com](http://www.TheAlzamendStory.com). The information contained therein or accessible thereby shall not be deemed to be incorporated into this Annual Report.

### **DESCRIPTION OF PROPERTY**

The Company currently maintains its corporate offices at the University of South Florida Incubator Center located next to the USF Innovation Center featuring shared labs and extensive research facility.

## RISK FACTORS

*An investment in our Common Stock involves a high degree of risk. You should carefully consider the risks described below, together with all of the other information included in this Annual Report, before making an investment decision. If any of the following risks actually occurs, our business, financial condition or results of operations could suffer. In that case, the trading price of our shares of Common Stock could decline and you may lose all or part of your investment. See “Cautionary Note Regarding Forward Looking Statements” above for a discussion of forward-looking statements and the significance of such statements in the context of this Annual Report.*

### **Risks Related to Our Company**

#### **We have virtually no operating history on which to judge our business prospects and management.**

The Company was incorporated on February 26, 2016 and only commenced operations thereafter. Accordingly, we have virtually no operating history upon which to base an evaluation of our business and prospects. Operating results for future periods are subject to numerous uncertainties and we cannot assure you that the Company will achieve or sustain profitability. The Company’s prospects must be considered in light of the risks encountered by companies in the early stage of development, particularly companies in new and rapidly evolving markets. Future operating results will depend upon many factors, including our success in attracting and retaining motivated and qualified personnel, our ability to establish short term credit lines or obtain financing from other sources, such as this Offering, our ability to develop and market new products, control costs, and general economic conditions. We cannot assure you that the Company will successfully address any of these contingencies.

#### **We are significantly influenced by our officers, directors and entities affiliated with them.**

In the aggregate, beneficial ownership of the Company’s shares of Common Stock by management and affiliated parties represents approximately 55.6% of fully diluted shares of Common Stock. These stockholders, if acting together, will be able to significantly influence all matters requiring approval by stockholders, including the election of directors and the approval of mergers or other business combinations transactions.

#### **Certain provisions of our Certificate of Incorporation could allow concentration of voting power in one stockholder, which may, among other things, delay or frustrate the removal of incumbent directors or a takeover attempt, even if such events may be beneficial to our stockholders.**

Provisions of our Certificate of Incorporation adopted by our Board may delay or frustrate the removal of incumbent directors and may prevent or delay a merger, tender offer or proxy contest involving the Company that is not approved by our Board, even if those events may be perceived to be in the best interests of our stockholders. Moreover, an affiliate of our company has acquired the Series A Preferred Stock described hereinafter. Such shares have significant voting power, among other terms. Further, the Company may designate and issue separate classes of preferred stock that may entitle its holder(s) to exercise significant control over us. Consequently, anyone to whom these shares are or were issued could have sufficient voting power to significantly influence if not control the outcome of all corporate matters submitted to the vote of our common stockholders. Those matters could include the election of directors, changes in the size and composition of the Board, and mergers and other business combinations involving the Company. In addition, through any such person’s control of the Board and voting power, the affiliate may be able to control certain decisions, including decisions regarding the qualification and appointment of officers, dividend policy, access to capital (including borrowing from third-party lenders and the issuance of additional debt or equity securities), and the acquisition or disposition of assets by the Company. In addition, the concentration of voting power in the hands of an affiliate could have the effect of delaying or preventing a change in control of the Company, even if the change in control would benefit our stockholders and may adversely affect the future market price of our Common Stock should a trading market therefor develop.

#### **Certain provisions of our Certificate of Incorporation and Bylaws and Delaware law make it more difficult for a third party to acquire us and make a takeover more difficult to complete, even if such a transaction were in the stockholders’ interest.**

Our Certificate of Incorporation and Bylaws and certain provisions of Delaware State law could have the effect of making it more difficult or more expensive for a third party to acquire, or discouraging a third party from attempting to acquire, control of the Company, even when these attempts may be in the best interests of our stockholders. For example, we are governed by Section 203 of the Delaware General Corporation Law. In general, Section 203 prohibits a public Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner. A “business combination” includes mergers, asset sales or other transactions resulting in a financial benefit to the stockholder. An “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years did own, 15% or more of the corporation’s outstanding voting stock. These provisions may have the effect of delaying, deferring or preventing a change in our control.

#### **Limitations of Director Liability and Indemnification of Directors and Officers and Employees.**

Our Certificate of Incorporation limits the liability of directors to the maximum extent permitted by Delaware law. Delaware law provides that directors of a corporation will not be personally liable for monetary damages for breach of their fiduciary duties as directors, except for liability for any:

- breach of their duty of loyalty to us or our stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- transaction from which the directors derived an improper personal benefit.

These limitations of liability do not apply to liabilities arising under the federal or state securities laws and do not affect the availability of equitable remedies such as injunctive relief or rescission.

Our bylaws provide that we will indemnify our directors, officers and employees to the fullest extent permitted by law. Our bylaws also provide that we are obligated to advance expenses incurred by a director or officer in advance of the final disposition of any action or proceeding. We believe that these bylaw provisions are necessary to attract and retain qualified persons as directors and officers.

The limitation of liability in our Certificate of Incorporation and bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against directors and officers, even though an action, if successful, might provide a benefit to us and our stockholders. Our results of operations and financial condition may be harmed to the extent we pay the costs of settlement and damage awards against directors and officers pursuant to these indemnification provisions.

#### **We will need but may be unable to obtain additional funding on satisfactory terms, which could dilute our stockholders or impose burdensome financial restrictions on our business.**

We have relied upon cash from financing activities and in the future, we hope to rely on revenues generated from operations to fund all of the cash requirements of our activities. However, there can be no assurance that we will be able to generate any significant cash from our operating activities in the future. Future financings may not be available on a timely basis, in sufficient amounts or on terms acceptable to us, if at all. Any debt financing or other financing of securities senior to the Common Stock will likely include financial and other covenants that will restrict our flexibility. Any failure to comply with these covenants would have a material adverse effect on our business, prospects, financial condition and results of operations because we could lose our existing sources of funding and impair our ability to secure new sources of funding. However, there can be no assurance that the Company will be able to generate any investor interest in its securities. If we do not obtain additional financing, our business will never commence, in which case you would likely lose the entirety of your investment in us.

#### **Our financial situation creates substantial doubt whether we will continue as a going concern**

Since inception, the Company has not generated revenues and has incurred losses. As of April 30, 2018, the Company had cash of \$545,001 and an accumulated deficit of \$2,513,137. The Company has incurred recurring losses and reported losses for the year ended April 30, 2018 of \$931,663. The report of the Company's independent registered public accounting firm on the Company's April 30, 2018 financial statements includes a going concern explanatory paragraph which states that there is substantial doubt regarding the Company's ability to continue as a going concern. There can be no assurances that we will be able to achieve a level of revenues adequate to generate sufficient cash flow from operations or obtain additional financing through private placements, public offerings and/or bank financing necessary to support our working capital requirements. To the extent that funds generated from any private placements, public offerings and/or bank financing are insufficient, we will have to raise additional working capital. No assurance can be given that additional financing will be available, or if available, will be on acceptable terms. If adequate working capital is not available we may be forced to discontinue operations, which would cause investors to lose their entire investment.

**We are at an early stage of development as a company and currently have no source of revenue and may never become profitable.**

We are a preclinical development stage biopharmaceutical company. Currently, we have no products approved for commercial sale and, to date, we have not generated any revenue. Our ability to generate revenue depends heavily on:

- demonstration in future clinical trials that LiProSal<sup>TM</sup> and CAO22W are safe and effective;
- our ability to seek and obtain regulatory approvals, including with respect to the indications we are seeking;
- successful manufacture and commercialization of LiProSal<sup>TM</sup> and CAO22W; and
- market acceptance of LiProSal<sup>TM</sup> and CAO22W.

We only have two product candidates, LiProSal<sup>TM</sup> and CAO22W, which are in the pre-IND stage and preclinical stage of development, respectively, and will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it and any successors could provide us with any revenue. As a result, if we do not successfully develop, achieve regulatory approval and commercialize LiProSal<sup>TM</sup> or CAO22W, we will be unable to generate any revenue for many years, if at all. We do not anticipate that we will generate revenue for a few years, at the earliest, or that we will achieve profitability for at least several years after generating material revenue, if at all. If we are unable to generate revenue, we will not become profitable, and we may be unable to continue our operations.

**We do not have any products that are approved for commercial sale and therefore do not expect to generate any revenues from product sales in the foreseeable future, if ever.**

We currently do not have any products that are approved for commercial sale. To date, we have funded our operations primarily from loans and sales of our securities. We have not received, and do not expect to receive for at least the next few years any revenues from the commercialization of LiProSal<sup>TM</sup> or CAO22W. To obtain revenues from sales of our future product candidates, if any, we must succeed, either alone or with third parties, in developing, obtaining regulatory approval for, manufacturing and marketing drugs with commercial potential. We may never succeed in these activities and may not generate sufficient revenues to continue our business operations or achieve profitability.

**We must effectively manage the growth of our operations, or our company will suffer**

Our initiation of operations has resulted in significantly higher operating expenses, which the net proceeds from this Offering, if any, are intended in part to offset. Expansion of our operations, to include the development of LiProSal<sup>TM</sup> and CAO22W, may also cause a significant demand on our management, finances and other resources. Our ability to manage the anticipated future growth, should it occur, will depend upon a significant expansion of our accounting and other internal management systems and the implementation and subsequent improvement of a variety of systems, procedures and controls. In addition, we intend to expand the Board and to establish an SAB. There can be no assurance that significant problems in these areas will not occur. Any failure to expand these areas and implement and improve LiProSal<sup>TM</sup> or CAO22W or our procedures and controls in an efficient manner at a pace consistent with our business could have a material adverse effect on our business, financial condition and results of operations. There can be no assurance that our attempts to expand our marketing, sales, manufacturing and customer support efforts will be successful or will result in additional sales or profitability in any future period.

#### **Risks Related to Our Product Candidates**

**We have both operational and financial milestones that must be met to maintain the licensing rights to our current technology and IP from the USF Research Foundations, Inc. or those rights may be terminated.**

There are certain initial license fees and milestone payments required to be paid by us to the Licensor pursuant to the terms of the License Agreements.

The License Agreement require the Company to pay royalty payments of four percent (4%) on net sales of products developed from the licensed technology for CAO22W while the License Agreements for LiProSal<sup>TM</sup> requires the Company to pay combined royalty payments of four and one-half percent (4.5%) on net sales of products developed from the licensed technology. The Company has already paid an initial license fee of \$200,000 for CAO22W and \$60,000 of an initial license fee of \$200,000 for LiProSal<sup>TM</sup>. As an additional licensing fee for the license of CAO22W, the Licensor received 3,601,809 shares of Common Stock. As an additional licensing fee for the license of the LiProSal<sup>TM</sup> technologies, the Licensor is entitled to receive that number of shares Common Stock equal to three percent (3%) of the sum of the total number of such shares issued and outstanding shares plus any securities that are convertible into or exercisable or exchangeable for shares of Common Stock until the Company has received a total of \$5 million in cash in exchange for the Company's equity securities. Additionally, the Company is required to pay milestone payments on the due dates to the Licensor for the license of the CAO22W technology and for the LiProSal<sup>TM</sup> technologies, as follows:

**CAO22W:**

<b>Payment</b>	<b>Due Date</b>	<b>Event</b>
\$ 50,000	September 30, 2019	Upon IDN application filing
\$ 50,000	12 months from IND application filing date	Upon first dosing of patient in first Phase I Clinical Trial
\$ 175,000	12 months from first patient dosed in Phase I	Upon Completion of first Phase I Clinical Trial
\$ 500,000	24 months from completion of first Phase I Trial	Upon Completion of first Phase II Clinical Trial
\$ 1,000,000	12 months from completion of the first Phase II Clinical Trial	Upon first patient treated in a Phase III Clinical Trial
\$ 10,000,000	7 years from the effective date of the agreement	Upon FDA BLA Approval

**LiProSal™:**

<b>Payment</b>	<b>Due Date</b>	<b>Event</b>
\$ 50,000	November 1, 2019	Pre-IND meeting
\$ 65,000	6 months from IND filing date	IND application filing
\$ 190,000	12 months from IND filing date	Upon first dosing of patient in a clinical trial
\$ 500,000	12 months from first patient dosing	Upon Completion of first clinical trial
\$ 1,250,000	12 months from completion of the first Phase II clinical trial	Upon first patient treated in a Phase III Clinical Trial
\$ 10,000,000	8 years from the Effective Date of the Agreement	Upon FDA Approval

None of the milestones was met as of the date of this Annual Report. If the Company fails to meet a milestone by the specified date, the Licensor may terminate the respective License Agreement. If the Licensor were to terminate either License Agreement for whatever reason, it would materially and adversely affect our business, financial position and future prospects and you would likely lose the entirety of your investment in us.

The Licensor was also granted a preemptive right to acquire such shares or other equity securities that may be issued from time to time by the Company while the Licensor remains the owner of any equity securities of the Company. Further, if the Company issues equity securities at a price per share that is less than the price paid by purchasers in a transaction for aggregate consideration of at least \$5,000,000, then the number of shares owned by the Licensor shall be increased upon such issuance. The amount of the increase shall be determined by multiplying the number of shares then owned by Licensor by a fraction; the numerator of which shall be equal to the number of shares of Common Stock outstanding immediately after the issuance of additional shares of common stock, and the denominator of which shall be equal to the sum of (i) the number of shares of Common Stock outstanding immediately prior to the issuance of additional shares of Common Stock plus (ii) the number of shares of Common Stock which the aggregate consideration for the total number of additional shares of Common Stock so issued would purchase at the Investment Price.

**If we fail to comply with our obligations in the agreements under which we license intellectual property and other rights from third parties or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business.**

We are a party to these License Agreements with the University and expect to enter into additional license agreements in the future. The existing License Agreements impose, and we expect that future license agreements will impose, various diligence, milestone payment, royalty, and other obligations on us. If we fail to comply with our obligations under these agreements, or we are subject to a bankruptcy, we may be required to make certain payments to the licensor, we may lose the exclusivity of our license, or the licensor may have the right to terminate the license, in which event we would not be able to develop or market products covered by the license. The Licensor may take any of these actions, including terminating the License upon 60 days' notice for any reason. Additionally, the milestone and other payments associated with these licenses will make it less profitable for us to develop our product candidates. If the Licensor were to terminate the License Agreement for whatever reason, it would materially and adversely affect our business, financial position and future prospects and you would likely lose the entirety of your investment in us.



In some cases, patent prosecution of our licensed technology is controlled solely by the licensor. If our licensors fail to obtain and maintain patent or other protection for the proprietary intellectual property we license from them, we could lose our rights to the intellectual property or our exclusivity with respect to those rights, and our competitors could market competing products using the intellectual property. In certain cases, we control the prosecution of patents resulting from licensed technology. In the event we breach any of our obligations related to such prosecution, we may incur significant liability to our licensing partners. Licensing of intellectual property is of critical importance to our business and involves complex legal, business, and scientific issues. Disputes may arise regarding intellectual property subject to a licensing agreement, including but not limited to:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- the sublicensing of patent and other rights;
- our diligence obligations under each of the license agreements and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our collaborators; and
- the priority of invention of patented technology.

If disputes over intellectual property and other rights that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates.

**We are substantially dependent on the success of our product candidates, which may not receive regulatory approval or be successfully commercialized.**

In the future, we hope to submit LiProSal<sup>TM</sup> and CAO22W and, potentially, other product candidates, for regulatory approval. Currently, however, neither LiProSal<sup>TM</sup> nor CAO22W has been submitted for regulatory approval, which would be required before we seek to initiate commercial distribution. To date, we have invested nearly all of our resources in establishing our company and the acquisition of the intellectual property of our product candidates, LiProSal<sup>TM</sup> and CAO22W. Our near-term prospects, including our ability to finance our company and to enter into strategic collaborations and, ultimately, to generate revenue, are directly dependent upon the successful development and commercialization of LiProSal<sup>TM</sup> or CAO22W.

The development and commercial success of our product will depend on a number of factors, including, without limitation, the following:

- timely initiation and successful completion of preclinical studies and clinical trials for LiProSal<sup>TM</sup> or CAO22W;
- demonstration to the satisfaction of the FDA, the EMA and other applicable regulatory authorities the safety and efficacy of LiProSal<sup>TM</sup> or CAO22W as well as to obtain regulatory and marketing approval for LiProSal<sup>TM</sup> or CAO22W in the U.S., Europe and elsewhere;
- continued compliance with all clinical and regulatory requirements applicable to LiProSal<sup>TM</sup> and CAO22W;
- maintenance of an acceptable safety profile of LiProSal<sup>TM</sup> and CAO22W following regulatory approval;
- competition with other treatments;
- creation, maintenance and protection of our intellectual property portfolio, including patents and trade secrets, and regulatory exclusivity for LiProSal<sup>TM</sup> and CAO22W;
- effectiveness of our and our eventual partners' marketing, sales and distribution strategy and operations;
- ability of our third-party manufacturers to manufacture supplies of our product and product candidates and to develop, validate and maintain commercially viable manufacturing processes;
- ability to launch commercial sales of LiProSal<sup>TM</sup> or CAO22W following regulatory approval, whether alone or in collaboration with others; and
- acceptance of LiProSal<sup>TM</sup> or CAO22W from physicians, health care payers, patients and the medical community.

Many of these factors are beyond our control, and we cannot assure you that we will ever be able to generate sufficient revenue or any revenue from the sale of LiProSal™ or CAO22W. Our failure in any of the above factors, or in successfully commercializing LiProSal™ or CAO22W on a timely basis, could have a material adverse effect on our business, results of operations and financial condition, and the value of your investment could substantially decline.

**LiProSal™ and CAO22W may not achieve market acceptance, which would limit our ability to generate revenue from new products.**

Even if we develop LiProSal™ or CAO22W and gain regulatory approvals for either or both, unless physicians and patients accept our product candidates, we may not be able to sell them and generate significant revenues. We cannot assure you that LiProSal™, CAO22W, or any other potential products, will achieve market acceptance and revenue if and when they obtain the requisite regulatory approvals. Market acceptance of any product candidate depends on a number of factors, including but not limited to:

- the indication and warnings approved by regulatory authorities in the product label;
- continued demonstration of efficacy and safety in commercial use;
- physicians' willingness to prescribe the product;
- reimbursement from third-party payors such as government health care systems and insurance companies;
- the price of the product;
- the nature of any post-approval risk management plans mandated by regulatory authorities;
- competition; and
- the effectiveness of marketing and distribution support.

Any failure by LiProSal™ or CAO22W to achieve market acceptance or commercial success could have a material adverse effect on our business, results of operations and financial condition.

**Problems in our manufacturing process, failure to comply with manufacturing regulations or unexpected increases in our manufacturing costs could harm our business, results of operations and financial condition.**

We are responsible for the manufacture and supply of LiProSal™ and CAO22W, independently of each other. The manufacturing of LiProSal™ and CAO22W necessitates compliance with the FDA, EU and international current Good Manufacturing Practice (“cGMP”) and other international regulatory requirements. Although we may in the future contract with third parties for a certain amount of the manufacturing of LiProSal™ and CAO22W, the responsibility to obtain market authorization for LiProSal™ and CAO22W remains with us. As such, even if we could potentially have a claim against one or more third parties, we are legally liable for any noncompliance related to LiProSal™ and CAO22W and we expect to retain legal responsibility for any future product candidates as well.

If we are unable to manufacture, or contract to manufacture, LiProSal™ and CAO22W in accordance with regulatory specifications, or if there are disruptions in the manufacturing process due to damage, loss or failure to pass regulatory inspections of manufacturing facilities, we may not be able to meet the demand for our products or supply sufficient product for use in clinical trials, and this may harm our ability to commercialize LiProSal™ and CAO22W on a timely or cost-competitive basis, or preclude us from doing so at all.

Before we can begin commercial manufacture of LiProSal™, CAO22W, or any other product candidate that we may develop in the future, we must obtain FDA regulatory approval for the product, which requires a successful FDA inspection of our manufacturing facilities, processes and quality systems in addition to other product-related approvals. Even if we successfully pass an FDA Pre-Approval Inspection of any manufacturing facilities we may establish or contract with, our pharmaceutical facilities would be continuously subject to inspection by the FDA and foreign regulatory authorities, even after product approval. Due to the complexity of the processes that we anticipate will eventually be used to manufacture LiProSal™ and CAO22W, we may be unable to pass federal, state or international regulatory inspections in a cost-effective manner, whether initially or at any time thereafter. If we are unable to comply with manufacturing regulations, we may be subject to fines, unanticipated compliance expenses, recall or seizure of any approved products, or legal actions such as injunctions or criminal or civil prosecution. These possible sanctions could materially and adversely affect our business, results of operations and financial condition. See also “Risks Related to Development and Regulatory Approval of Our Product.” The regulatory approval process is uncertain, requires us to utilize significant resources, and may prevent us or our commercial partners from obtaining approvals for the commercialization of some or all of our drug candidates.”

**We expect to face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.**

The development and commercialization of new therapy and vaccine products is highly competitive. We will face competition with respect to LiProSal<sup>TM</sup>, CAO22W and any other product candidates that we may seek to develop or commercialize in the future, from major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies worldwide. In addition to existing therapeutic treatments for the indications we are targeting with LiProSal<sup>TM</sup> and CAO22W, we also face potential competition from other drug candidates in development by other companies. Our potential competitors include large health care companies, such as Celgene Corporation, Merck & Co., Inc., Sanofi S.A., Eli Lilly and Company, Bayer AG, Novartis AG and Boehringer Ingelheim GmbH. We also know of several smaller early stage companies that are developing products for use in our segment of the market. Some of the potential competitive compounds referred to above are being developed by large, well-financed and established pharmaceutical and biotechnology companies or have been partnered with such companies, which may give them development, regulatory and marketing advantages over our products.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any products that we may develop. Our competitors also may obtain FDA or other regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. In addition, our ability to compete may be affected in many cases by insurers or other third-party payers seeking to encourage the use of generic products. If LiProSal<sup>TM</sup> or CAO22W achieves marketing approval, we expect that it will be priced at a significant premium over competing generic products.

Some of the companies against which we are competing or against which we may compete in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved products than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated among a smaller number of our competitors. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These third parties compete with us in recruiting and retaining qualified scientific and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or necessary for, our programs.

If we are unable to compete successfully, we may be unable to grow and sustain our revenue, which could materially and adversely affect our business, results of operations and financial condition.

**Serious adverse events or other safety risks could require us to abandon development and preclude, delay or limit approval of LiProSal<sup>TM</sup> or CAO22W, or limit the scope of any approved label or market acceptance.**

If LiProSal<sup>TM</sup>, CAO22W or any other product candidate that we may develop in the future, prior to or after any approval for commercial sale, causes serious or unexpected side effects, or become associated with other safety risks such as misuse, abuse or diversion, a number of potentially significant negative consequences could result, including, without limitation:

- regulatory authorities may interrupt, delay or halt clinical trials;
- regulatory authorities may deny regulatory approval of LiProSal<sup>TM</sup> or CAO22W;
- regulatory authorities may require certain labeling statements, such as warnings or contraindications or limitations on the indications for use, or impose restrictions on distribution in the form of a Risk Evaluation and Mitigation Strategy “REMS”), in connection with approval, if any;
- regulatory authorities may withdraw their approval, require more onerous labeling statements or impose a more restrictive REMS of any product that is approved;
- we may be required to change the way the product is administered or conduct additional clinical trials;
- any relationships that we may be able to form in the future with any commercial partners may suffer;
- we could be sued and held liable for harm caused to patients; and
- our reputation may suffer.

We may voluntarily suspend or terminate our clinical trials if at any time we believe that they present an unacceptable risk to participants or if preliminary data demonstrate that either CAO22W or LiProSal<sup>TM</sup> are unlikely to receive regulatory approval or is unlikely to be successfully commercialized. In addition, regulatory agencies, an Institutional Review Board, or data safety monitoring boards may at any time recommend the temporary or permanent discontinuation of our clinical trials or request that we cease using investigators in the clinical trials if they believe that the clinical trials are not being conducted in accordance with applicable regulatory requirements, or that they present an unacceptable safety risk to participants. If we elect or are forced to suspend or terminate a clinical trial of LiProSal<sup>TM</sup>, CAO22W or any other product candidate that we may in the future develop, the commercial prospects for that product will be harmed and our ability to generate product revenue from that product may be delayed or eliminated. Furthermore, any of these events could prevent us or our partners from achieving or maintaining market acceptance of the affected product and could substantially increase the costs of commercializing LiProSal<sup>TM</sup> or CAO22W and materially impair our ability to generate revenue from the commercialization of LiProSal<sup>TM</sup> or CAO22W either by us or by any commercial partners that we may develop a relationship with in the future and could have a material adverse effect on our reputation, business, results of operations and financial condition.

**If we fail to obtain and sustain an adequate level of reimbursement for our products by third-party payers, sales and profitability will be adversely affected.**

The course of medical treatment for human patients is, and will continue to be, expensive. We expect that most patients and their families will not be capable of paying for our products themselves. Accordingly, it is unlikely that there will be a commercially viable market for LiProSal<sup>TM</sup> or CAO22W without reimbursement from third-party payers. Additionally, even if there is a commercially viable market, if the level of third-party reimbursement is insufficient from the patient's perspective, our revenue and gross margins will be materially and adversely affected.

A current trend in the U.S. health care industry, as well as in other countries around the world, is toward cost containment. Large public and private payers, managed care organizations, group purchasing organizations and similar organizations are exerting increasing influence on decisions regarding the use of, and reimbursement levels for, particular treatments. Third-party payers, such as government programs, including Medicare in the U.S., and private health care insurers, carefully review and have increasingly been challenging the coverage of, and prices charged for, medical products and services. Many third-party payers limit coverage of or reimbursement for newly-approved health care products. Reimbursement rates from private health insurance companies vary depending on the company, the insurance plan and other factors. Cost-control initiatives could decrease the price we or our partners establish for products, which could result in lower product revenue and profitability.

Reimbursement systems in international markets vary significantly by country and by region, and reimbursement approvals must be obtained on a country-by-country basis. Our eventual partners may elect to reduce the price of our products in order to increase the likelihood of obtaining reimbursement approvals. In many countries, products cannot be commercially launched until reimbursement is approved and the negotiation process in some countries can exceed 12 months. In addition, pricing and reimbursement decisions in certain countries can be affected by decisions taken in other countries, which can lead to mandatory price reductions and/or additional reimbursement restrictions across a number of other countries, which may adversely affect our sales and profitability. If countries set prices that are not sufficient to allow us or our partners to generate a profit, our partners may refuse to launch the product in such countries or withdraw the product from the market, which would adversely affect our sales and profitability and could materially and adversely affect our business, results of operations and financial condition.

**We may not be successful in our efforts to expand our pipeline of product candidates.**

One element of our strategy is to expand our pipeline of pharmaceuticals based on our technology and advance these product candidates through clinical development for the treatment of a variety of indications. Although our research and development efforts to date have resulted in a number of development programs based on our technology, we may not ultimately be able to develop product candidates that are safe and effective. Even if we are successful in continuing to expand our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including as a result of being shown to have harmful side effects or other characteristics that indicate that they are unlikely to receive marketing approval and achieve market acceptance. In addition, if we attempt to apply our technology to develop product candidates for indications outside of Alzheimer's, we will need to conduct genotoxicity and immunotoxicity trials, in which the results are presently uncertain. If we do not successfully develop and commercialize product candidates based upon our technological approach, we will not be able to obtain product revenue in future periods, which would make it unlikely that we would ever achieve profitability.

**Product recalls or inventory losses caused by unforeseen events, cold chain interruption and testing difficulties may adversely affect our operating results and financial condition.**

LiProSal<sup>TM</sup> and CAO22W, individually, will be manufactured and distributed, if ever, using technically complex processes requiring specialized facilities, highly specific raw materials and other production constraints. The complexity of these processes, as well as the strict company and government standards for the manufacture of our products, will subject us to production risks. While product batches released for use in clinical trials or for commercialization undergo sample testing, some defects may only be identified following product release. In addition, process deviations or unanticipated effects of approved process changes may result in these intermediate products not complying with stability requirements or specifications. Most of our products must be stored and transported at temperatures within a certain range, which is known as “strict cold chain” storage and transportation. If these environmental conditions deviate, our products’ remaining shelf lives could be impaired or their efficacy and safety could become adversely affected, making them no longer suitable for use. The occurrence or suspected occurrence of production and distribution difficulties can lead to lost inventories, and in some cases product recalls, with consequential reputational damage and the risk of product liability. The investigation and remediation of any identified problems can cause production delays, substantial expense, lost sales and delays of new product launches, any of which could have a material adverse effect on our business, results of operations and financial condition.

### **Risks Related to Development and Regulatory Approval of Our Product**

#### **There is a high rate of failure for drug candidates proceeding through clinical trials.**

Generally speaking, there is a high rate of failure for drug candidates proceeding through clinical trials. We may suffer significant setbacks in our clinical trials similar to the experience of a number of other companies in the pharmaceutical and biotechnology industries, even after receiving promising results in earlier trials. Further, even if we view the results of a clinical trial to be positive, the FDA or other regulatory authorities may disagree with our interpretation of the data. For instance, any such differing interpretation could cause the FDA to require additional trials. In the event that:

- we obtain negative results from the LiProSal<sup>TM</sup> or CAO22W from a clinical trial;
- the FDA places a clinical hold on our clinical trials due to potential chemistry, manufacturing and controls issues or other hurdles, or
- the FDA does not approve our NDA for LiProSal<sup>TM</sup> or our BLA for CAO22W, then:
  - o we may not be able to generate sufficient revenue or obtain financing to continue our operations;
  - o our ability to execute our current business plan will be materially impaired;
  - o our reputation in the industry and in the investment community would likely be significantly damaged, and
  - o the price of the Common Stock, assuming a trading market has then developed therefor, would likely decrease significantly.

Any of these results could materially and adversely affect our business, results of operations or financial condition.

#### **Clinical trials for LiProSal<sup>TM</sup> or CAO22W can be expensive, time consuming, uncertain and susceptible to change, delay or termination.**

Clinical trials are expensive, time consuming and difficult to design and implement. The result of a clinical trial may be undesirable and can result in a clinical trial cancellation or the need for re-evaluation and supplementation. Even if the results of our clinical trials are favorable, the clinical trials for LiProSal<sup>TM</sup> or CAO22W are expected to continue for a few years and may even take significantly longer to complete. In addition, we, the FDA, an IRB, or other regulatory authority, including in the U.S., EU and elsewhere, may suspend, delay or terminate our clinical trials at any time, for various reasons, including, without limitation:

- lack of effectiveness of LiProSal<sup>TM</sup> or CAO22W during clinical trials;
- discovery of serious or unexpected toxicities or side effects experienced by trial participants or other safety issues;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- difficulty in retaining subjects who have initiated a clinical trial but may have withdrawn due to adverse side effects from the therapy, insufficient efficacy, fatigue with the clinical trial process or for any other reason;
- delays or inability in manufacturing or obtaining sufficient quantities of materials for use in clinical trials due to manufacturing or regulatory constraints;
- inadequacy of or changes in our manufacturing process or product formulation;
- delays in obtaining regulatory authorization to commence a trial, including experiencing “clinical holds” or delays requiring suspension or termination of a trial by a regulatory agency, such as the FDA, before or after a trial is commenced;
- changes in applicable regulatory policies and regulations;

- delays or failure in reaching agreement on acceptable terms in clinical trial contracts or protocols with prospective clinical trial sites;
- delay or failure to supply product for use in clinical trials which conforms to regulatory specification;
- unfavorable results from ongoing pre-clinical studies and clinical trials;
- failure of any contract research organizations (“CROs”) that we may partner with in the future, or other third-party contractors, to comply with all contractual requirements or to perform their services in a timely or acceptable manner;
- failure by us, our employees, any CROs or their employees to comply with all applicable FDA or other regulatory requirements relating to the conduct of clinical trials;
- scheduling conflicts with participating clinicians and clinical institutions;
- failure to design appropriate clinical trial protocols; or
- regulatory concerns with pharmaceutical products generally and the potential for abuse.

Any of the foregoing could have a material adverse effect on our business, results of operations and financial condition.

**The regulatory approval process is uncertain, requires us to utilize significant resources, and may prevent us or our commercial partners from obtaining approvals for the commercialization of LiProSal™ or CAO22W.**

The research, testing, manufacturing, labeling, approval, sale, marketing and testing of LiProSal™ and CAO22W are and will be subject to extensive regulation by regulatory authorities in the U.S., Europe and elsewhere, and regulatory requirements applicable to our product differ from country to country. Neither we nor any commercial partner is permitted to market any of our current or future product candidates in the U.S. until we receive approval from the FDA of either an NDA or BLA, respectively. Obtaining approval of an NDA or a BLA can be an uncertain process that requires us to utilize significant resources. Furthermore, regulatory authorities possess broad discretion regarding processing time and usually request additional information and raise questions which have to be answered. There is considerable uncertainty regarding the times at which products may be approved. In addition, failure to comply with FDA and other applicable U.S. and foreign regulatory requirements may subject us to administrative or judicially imposed sanctions, including: warning letters, civil and criminal penalties, injunctions, withdrawal of approved products from the market, product seizure or detention, product recalls, total or partial suspension of production, and refusal to approve pending applications or supplements to approved applications.

The process required by the FDA and most foreign regulatory authorities before human health care pharmaceuticals may be marketed generally involves nonclinical laboratory and, in some cases, animal tests; submission of an IND, which must become effective before clinical trials may begin; adequate and well-controlled human clinical trials to establish the safety and efficacy of the proposed drug for its intended use or uses; pre-approval inspection of manufacturing facilities and clinical trial sites; and FDA approval of a NDA or BLA, which must occur before a drug can be marketed or sold.

Regulatory approval of an NDA or BLA, or any supplement thereof, is not guaranteed, and the approval process requires us to utilize significant resources, could take several years, and is subject to the substantial discretion of the FDA. Despite the time and expense exerted, failure can occur at any stage, and we could encounter problems that cause us to abandon or have to repeat or perform additional studies. If our product or any of our future product candidates fails to demonstrate safety and efficacy in our studies, or for any other reason does not gain regulatory approval, our business and results of operations will be materially and adversely harmed.

In addition, separate regulatory approvals are required in order to market any product in many jurisdictions, including the U.S., the European Economic Area, which consists of the 28 Member States of the European Union plus Norway, Iceland and Liechtenstein, and many others. Approval procedures vary among countries and can involve additional studies and testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Studies conducted in one country may not be accepted by regulatory authorities in other countries. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one or more foreign regulatory authorities does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory process in others. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval. We may be unable to file for regulatory approvals or do so on a timely basis and, even if we are able to, we may not receive necessary approvals to commercialize our products in any market. Any of these results could have a material adverse effect on our business, results of operations and financial condition.

**Even if we receive regulatory approval for any of our future product candidates, we will be subject to ongoing FDA and other regulatory body obligations and continued regulatory review, which may result in significant additional expense. Additionally, our product candidates, if any, if approved, will be subject to labeling and manufacturing requirements and could be subject to other restrictions. Failure to comply with these regulatory requirements or the occurrence of unanticipated problems with our products could result in significant penalties.**

Any regulatory approvals that we or any of our collaborators receive for LiProSal<sup>TM</sup>, CAO22W or any future product candidate may be subject to conditions of approval or limitations on the approved indicated uses for which the product may be marketed or may contain requirements for potentially costly surveillance to monitor the safety and efficacy of the product candidate. In addition, LiProSal<sup>TM</sup>, CAO22W and any of our future product candidates, if approved by the FDA or other regulatory bodies, will be subject to extensive and ongoing regulatory requirements regarding the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion and recordkeeping. These requirements will include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP, Good Laboratory Practice and Good Clinical Practice for any studies that we conduct post-approval. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with our third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters or holds on target studies;
- refusal by the FDA or other applicable regulatory body to approve pending applications or supplements to approved applications filed by us or our strategic collaborators, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The policies of the FDA and other regulatory bodies may change, and additional government regulations may be promulgated that could prevent, limit or delay regulatory approval of LiProSal<sup>TM</sup> or CAO22W. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the U.S. or elsewhere. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we may have obtained, and we may not achieve or sustain profitability, which would materially and adversely affect our business, results of operations and financial condition.

**LiProSal<sup>TM</sup> or CAO22W and any of our future product candidates, if approved, may cause or contribute to adverse medical events that we are required to report to the FDA and regulatory authorities in other countries and, if we fail to do so, we could be subject to sanctions that would materially harm our business.**

If we are successful in commercializing LiProSal<sup>TM</sup>, CAO22W or any of our future product candidates, regulations promulgated by the FDA and by the regulatory authorities in other countries require that we report certain information about adverse medical events if those products may have caused or contributed to those adverse events. The timing of our obligation to report would be triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events we become aware of within the prescribed timeframe. We may also fail to appreciate that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of our products. If we fail to comply with our reporting obligations, the FDA and regulatory authorities in other countries could take action including criminal prosecution, the imposition of civil monetary penalties, seizure of our products, or delay in approval or clearance of future products, which could have a material adverse effect on our business, results of operations and financial condition.



**Legislative or regulatory reforms with respect to products may make it more difficult and costly for us to obtain regulatory clearance or approval of LiProSal™, CAO22W or any of our future product candidates and to produce, market, and distribute our products after clearance or approval is obtained.**

From time to time, legislation is drafted and introduced in the U.S. Congress and lawmaking bodies in other countries that could significantly change the statutory provisions governing the testing, regulatory clearance or approval, manufacture, and marketing of regulated products. In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Similar changes in regulations can occur in other countries. Any new regulations or revisions or reinterpretations of existing regulations in the U.S. or in other countries may impose additional costs or lengthen review times of LiProSal™, CAO22W and any of our future product candidates. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require:

- requests for additional endpoints or studies;
- changes to manufacturing methods;
- recall, replacement, or discontinuance of certain products; and
- additional record keeping.

Each of these would likely entail substantial time and cost and could have a material adverse effect on our ability to obtain regulatory approval for our product candidates. In addition, delays in receipt of or failure to receive regulatory clearances or approvals for any future products could materially and adversely affect our business, results of operations and financial condition.

**Our ability to market LiProSal™, CAO22W and any future product candidates in the U.S., if approved, will be limited to use for the treatment of the indications for which they are approved, and if we want to expand the indications for which we may market LiProSal™, CAO22W and any future product candidates, we will need to obtain additional FDA approvals, which may not be granted.**

We plan to seek full FDA approval in the U.S. for LiProSal™ and CAO22W to treat Alzheimer's disease. If LiProSal™ or CAO22W is approved, the FDA will restrict our ability to market or advertise it for the treatment of indications other than the one for which it is approved, which could limit its use. If we decide to attempt to develop, promote and commercialize new treatment indications and protocols for LiProSal™, CAO22W and product candidates in the future, we could not predict when, or if, we would ever receive the approvals required to do so. We would be required to conduct additional studies to support such applications for additional use, which would consume additional resources and may produce results that do not result in FDA approvals. If we do not obtain additional FDA approvals, our ability to expand our business in the U.S. would be adversely affected, which could materially and adversely affect our business, results of operations and financial condition.

**The anticipated development of a REMS for LiProSal™ or CAO22W could cause delays in the approval process and would add additional layers of regulatory requirements that could impact our ability to commercialize LiProSal™ and CAO22W in the U.S. and reduce their market potential.**

As a condition of approval of an NDA or a BLA, the FDA may require a REMS to ensure that the benefits of the drug outweigh the potential risks. REMS elements can include medication guides, communication plans for health care professionals, and elements to assure safe use (“ETASU”). ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug's safety or efficacy. We may be required to adopt a REMS for LiProSal™ or CAO22W to ensure that the benefits outweigh the risks of abuse, misuse, diversion and other potential safety concerns. Even if the risk of abuse, misuse or diversion are not as high as for some other products, there can be no assurance that the FDA will approve a manageable REMS for LiProSal™ or CAO22W, which could create material and significant limits on our ability to successfully commercialize LiProSal™ and CAO22W in the U.S. Delays in the REMS approval process could result in delays in the NDA or BLA approval process, respectively. In addition, as part of the REMS, the FDA could require significant restrictions, such as restrictions on the prescription, distribution and patient use of the product, which could significantly impact our ability to effectively commercialize LiProSal™ or CAO22W, and dramatically reduce their market potential thereby adversely impacting our business, financial condition and results of operations. Even if initial REMS are not highly restrictive, if, after launch, LiProSal™, CAO22W and other drug candidates were to be subject to significant abuse/non-medical use or diversion from licit channels, this could lead to negative regulatory consequences, including a more restrictive REMS, which could materially and adversely affect our business, results of operations and financial condition.

**If we are found in violation of “fraud and abuse” laws, we may be required to pay a penalty and/or be suspended from participation in government-run health care programs, which may adversely affect our business, financial condition and results of operations.**

If we are successful in obtaining marketing approval for our products in the U.S. and elsewhere, we will be subject to various health care “fraud and abuse” laws, including anti-kickback laws, false claims laws and other laws intended to reduce fraud and abuse in government-run health care programs, which could affect us, particularly upon successful commercialization of our products in the U.S. For example, the Medicare and Medicaid Patient Protection Act of 1987 (otherwise known as the federal “*Anti-Kickback Statute*”) makes it illegal for any person, including a prescription drug manufacturer (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration that is intended to induce the referral of business, including the purchase, order or prescription of a particular drug for which payment may be made under a U.S. health care program such as Medicare or Medicaid. Under U.S. federal government regulations, some arrangements, known as safe harbors, are deemed not to violate the Anti-Kickback Statute. Although we intend to seek to structure our business arrangements in compliance with all applicable requirements, these laws are broadly written, and it is often difficult to determine precisely how the law will be applied in specific circumstances. Accordingly, it is possible that our practices may be challenged under the Anti-Kickback Statute and similar laws in other jurisdictions. False claims laws prohibit anyone from knowingly and willfully presenting or causing to be presented for payment to third-party payers, including government payers, reimbursement claims for drugs or services that are false or fraudulent, claims for items or services that were not provided as claimed, or claims for medically unnecessary items or services. Cases have been brought under false claims laws alleging that off-label promotion of pharmaceutical products or the payment of kickbacks to pharmaceutical providers has resulted in the submission of false claims to governmental health care programs. Under laws such as the Health Insurance Portability and Accountability Act of 1996 in the U.S., we are prohibited from knowingly and willfully executing a scheme to defraud any health care benefit program, including private payers, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for health care benefits, items or services. Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including fines and/or exclusion or suspension from government-run health care programs such as Medicare and Medicaid and debarment from contracting with the U.S. and other governments. In addition, in the U.S. individuals have the ability to bring actions on behalf of the government under the federal False Claims Act as well as under state false claims laws.

Many states in the U.S. have adopted laws similar to the Anti-Kickback Statute, some of which apply to the referral of patients for health care services reimbursed by any source, not just governmental payers. In addition, California and a few other states in the U.S. have passed laws that require pharmaceutical companies to comply with the April 2003 Office of Inspector General Compliance Program Guidance for Pharmaceutical Manufacturers and/or the Pharmaceutical Research and Manufacturers of America Code on Interactions with Health Care Professionals. In addition, several states impose other marketing restrictions or require pharmaceutical companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements and if we fail to comply with an applicable state law requirement we could be subject to penalties.

We have yet to receive definitive guidance on the application of fraud and abuse laws to our business. Law enforcement authorities are increasingly focused on enforcing these laws, and it is possible that some of our future practices may be challenged under these laws. While we believe we will be able to structure our business arrangements to comply with these laws, it is possible that the government could in the future allege violations of, or convict us of violating, these laws. If we are found in violation of one of these laws, we could be required to pay a penalty and could be suspended or excluded from participation in certain government-run health care programs, and our business, results of operations and financial condition may be materially and adversely affected.

### **Risks Related to Our Business and Industry**

**If we fail to attract and keep senior management and key scientific personnel, we may be unable to successfully develop LiProSal™, CAO22W or any future product candidates, conduct our in-licensing and development efforts or commercialize LiProSal™, CAO22W or any of our future product candidates.**

Our future growth and success depends in part on our continued ability to attract, retain and motivate highly qualified management and scientific personnel. We are highly dependent upon our senior management, particularly Stephan Jackman, our Chief Executive Officer, Kenneth Cragun, our Chief Financial Officer as well as on Dr. Chuanhai Cao, the neuroscientist who developed CAO22W, as well as the senior scientists on Dr. Cao's medical research team, Dr. Roland "Doug" Shytle and Dr. Jun Tan, two of the investors of LiProSal™ and other members of our senior management team. The loss of services of any of these individuals could delay or prevent the successful development of our current or future product pipeline, completion of our planned development efforts or the commercialization of LiProSal™ or CAO22W. It is possible that current or former employees of the Company could put forward claims for an alleged right to our patents and demand compensation therefor. If one or more of the key personnel were to leave us and engage in competing operations, our business, results of operations and financial condition could be materially and adversely affected. To date, none of our key personnel has left us or, to our knowledge, engaged in competing operations, nor has any departure of key personnel had any material effect on our company.

**We may have trouble hiring additional qualified personnel.**

As we expand our development and commercial activities, we will need to hire additional personnel and could experience difficulties attracting and retaining qualified employees. Competition for qualified personnel in the biopharmaceutical field is intense due to the limited number of individuals who possess the skills and experience required by that industry. We may not be able to attract and retain quality personnel on favorable terms, or at all. In addition, to the extent we hire personnel from competitors, we may be subject to allegations that such personnel have been improperly solicited or that they have divulged proprietary or other confidential information, or that their former employers own their research output. Any of these difficulties could have a material adverse effect on our business, results of operations and financial condition.

**We are subject to risks relating to legal proceedings.**

We are subject to various claims and legal actions arising in the ordinary course of our business. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence of any such litigation could harm our business, results of operations and financial condition. Results of actual and potential litigation are inherently uncertain. An unfavorable result in a legal proceeding could adversely affect our reputation, financial condition and operating results.

**If product liability lawsuits are brought against us, we will incur substantial liabilities and may be required to limit the commercialization of LiProSal™ or CAO22W.**

We and our partners face potential product liability exposure related to the testing of LiProSal™ or CAO22W in clinical trials. We will face exposure to claims by an even greater number of persons if we begin to market and distribute our products commercially in the U.S. and elsewhere, including those relating to misuse of LiProSal™ or CAO22W. Now, and in the future, an individual may bring a liability claim against us alleging that LiProSal™ or CAO22W caused an injury. While we intend to take what we believe to be appropriate precautions, we may be unable to avoid significant liability if any product liability lawsuit is brought against us. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities. Even if we successfully defend any such action, the costs associated with such defense could prove exorbitant. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for LiProSal™ or CAO22W, if such product candidate is approved;
- injury to our reputation;
- withdrawal of clinical trial participants;
- costs of related litigation;
- substantial monetary awards to patients and others;
- increased cost of liability insurance;
- loss of revenue; and
- our inability to successfully commercialize our products.

Furthermore, in the future there may be a need to expand the scope of our insurance coverage, which could result in significantly increased costs or the inability to obtain sufficient insurance coverage. Any of these occurrences could have a material adverse effect on our business, results of operations and financial condition.

**Failure of our information technology systems could significantly disrupt the operation of our business.**

Our ability to execute our business plan and to comply with regulatory requirements with respect to data control and data integrity depends, in part, on the continued and uninterrupted performance of our information technology systems (“*IT systems*”). These systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, there are no assurances that electronic break-ins, computer viruses and similar disruptive problems, and/or sustained or repeated system failures or problems arising during the upgrade of any of our IT systems that interrupt our ability to generate and maintain data will not occur. The occurrence of any of the foregoing with respect to our IT systems could have a material adverse effect on our business, results of operations or financial condition.

**We will be subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our anticipated operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.**

Our operations, if initiated, will be subject to certain anti-corruption laws, including the U.S. Foreign Corrupt Practices Act (“*FCPA*”), and other anti-corruption laws that apply in countries where we do business. The FCPA and other anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential FCPA violations and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

We also anticipate becoming subject to other laws and regulations governing our international operations, including regulations administered in the U.S. and in the EU, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations (collectively, “*Trade Control Laws*”).

There can be no assurance that we will be completely effective in ensuring our compliance with all applicable anticorruption laws, including the FCPA or other legal requirements, such as Trade Control Laws. Any investigation of potential violations of the FCPA, other anti-corruption laws or Trade Control Laws by U.S., EU or other authorities could have an adverse impact on our reputation, our business, results of operations and financial condition. Furthermore, should we be found not to be in compliance with the FCPA, other anti-corruption laws or Trade Control Laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, as well as the accompanying legal expenses, any of which could have a material adverse effect on our reputation and liquidity, as well as on our business, results of operations and financial condition.

**Risks Related to Our Intellectual Property**

**We may be forced to litigate to enforce or defend our intellectual property rights, or the intellectual property rights of our licensors.**

We may be forced to litigate to enforce or defend our intellectual property rights against infringement and unauthorized use by competitors. In so doing, we may place our intellectual property at risk of being invalidated, held unenforceable, or narrowed in scope. Further, an adverse result in any litigation or defense proceedings may place pending applications at risk of non-issuance. In addition, if any licensor fails to enforce or defend its intellectual property rights, this may adversely affect our ability to develop and commercialize LiProSal<sup>TM</sup> or CAO22W as well as our ability to prevent competitors from making, using, and selling competing products. Any such litigation could be very costly and could distract our management from focusing on operating our business. The existence or outcome of any such litigation could harm our business, results of operations and financial condition.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our Common Stock, should a market therefor ever develop.

**We may be unable to adequately prevent disclosure of trade secrets and other proprietary information.**

We rely on trade secrets to protect our proprietary know-how and technological advances, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to protect our trade secrets and other proprietary information. These agreements may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. Failure to obtain or maintain trade secret protection or failure to adequately protect our intellectual property could enable competitors to develop generic products or use our proprietary information to develop other products that compete with our products or cause additional, material adverse effects upon our business, results of operations and financial condition.

The transfer of technology and knowledge to contract manufacturers pursuant to the production of our products also creates a risk of uncontrolled distribution and copying of concepts, methods and processes relating to our products. Such uncontrolled distribution and copying could have a material adverse effect on the value of our products if used for the production of competing drugs or otherwise used commercially without our obtaining financial compensation.

**We may become subject to third parties' claims alleging infringement of patents and proprietary rights or seeking to invalidate our patents or proprietary rights, which would be costly, time-consuming and, if successfully asserted against us, delay or prevent the development and commercialization of LiProSal<sup>TM</sup> or CAO22W.**

There has been substantial litigation and other proceedings regarding patent and other intellectual property rights in the pharmaceutical industry, as well as patent challenge proceedings, including interference and administrative law proceedings before the U.S. Patent and Trademark Office ("*U.S. PTO*") and the European Patent Office ("*EPO*"), and oppositions and other comparable proceedings in other jurisdictions. Recently, under U.S. patent reform laws, new procedures including inter partes review and post grant review have been implemented. As stated below, the novel implementation of such reform laws presents uncertainty regarding the outcome of challenges to our patents in the future.

We cannot assure you that LiProSal<sup>TM</sup>, CAO22W or any of our future product candidates will not infringe existing or future patents. We may be unaware of patents that have already issued that a third party might assert are infringed by LiProSal<sup>TM</sup>, CAO22W or one of our future product candidates. Because patent applications can take many years to issue and may be confidential for eighteen months or more after filing, there may be applications now pending of which we are unaware of and which may later result in issued patents that we may infringe by commercializing LiProSal<sup>TM</sup>, CAO22W or any of our future product candidates. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Moreover, we may face claims from non-practicing entities (commonly referred to as patent trolls), which have no relevant product revenue and against whom our own patent portfolio may thus have no deterrent effect.

We may be subject to third-party claims in the future against us or our collaborators that would cause us to incur substantial expenses and, if successful against us, could cause us to pay substantial damages, including treble damages and attorney's fees if we are found to be willfully infringing a third party's patents. If a patent infringement suit were brought against us or our collaborators, we or our collaborators could be forced to stop or delay research, development, manufacturing or sales of LiProSal<sup>TM</sup> or CAO22W. As a result of patent infringement claims, or in order to avoid potential claims, we or our collaborators may choose to seek, or be required to seek, a license from the third party and would most likely be required to pay license fees or royalties or both. These licenses may not be available on acceptable terms, or at all. Even if we or our collaborators were able to obtain a license, the rights may be nonexclusive, which would give our competitors access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or forced to redesign it, or to cease some aspect of our business operations if, as a result of actual or threatened patent infringement claims, we or our collaborators are unable to enter into licenses on acceptable terms. Even if we are successful in defending such claims, infringement and other intellectual property litigation can be expensive and time-consuming to litigate and divert management's attention from our core business. Any of these events could harm our business significantly.

In addition to infringement claims against us, if third parties have prepared and filed patent applications in the U.S. that also claim technology to which we have rights, we may have to participate in interference proceedings in the U.S. PTO to determine the priority of invention. Third parties may also attempt to initiate reexamination, post grant review or inter partes review of our patents in the U.S. PTO. We may also become involved in similar opposition proceedings in the EPO or comparable offices in other jurisdictions regarding our intellectual property rights with respect to our products and technology. Any of these claims could have a material adverse effect on our business, results of operations and financial condition.

**If our efforts to protect the proprietary nature of the intellectual property related to LiProSal<sup>TM</sup>, CAO22W or any of our potential future product candidates are not adequate, we may not be able to compete effectively in our market.**

We expect to rely upon a combination of patents, trade secret protection as well as confidentiality and license agreements to protect the intellectual property related to our product and our current product candidates and our development programs.

Composition-of-matter patents on an active pharmaceutical ingredient are generally considered to be the strongest form of intellectual property protection for pharmaceutical products, as such patents provide protection without regard to any particular method of use or manufacture. We cannot be certain that the claims in any patent application that we may submit covering composition-of-matter of LiProSal<sup>TM</sup>, CAO22W and any potential future product candidates will be considered patentable by the U.S. PTO and courts in the U.S., or by the patent offices and courts in foreign countries. Method-of-use patents protect the use of a product for the specified method. This type of patent does not prevent a competitor from making and marketing a product that is identical to our product for an indication that is outside the scope of the patented method.

The strength of patents involves complex legal and scientific questions and can be uncertain. The patent applications that we may in the future own or license may fail to result in issued patents in the U.S. or in other foreign countries. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, any of our future patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the patent applications we may in the future own, in-license or pursue with respect to LiProSal<sup>TM</sup>, CAO22W or any future product candidates is threatened, it could threaten our ability to commercialize LiProSal<sup>TM</sup>, CAO22W or any future product candidates. Further, if we encounter delays in our development efforts, the period of time during which we could market LiProSal<sup>TM</sup>, CAO22W or any future product candidates under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to LiProSal<sup>TM</sup>, CAO22W, or any future product candidates.

Even where laws provide protection, costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights, and the outcome of such litigation would be uncertain. Moreover, any actions we may bring to enforce our intellectual property against our competitors could provoke them to bring counterclaims against us, and some of our competitors have substantially greater intellectual property portfolios than we have.

We will also rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we endeavor to execute confidentiality agreements with all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology, we cannot be certain that we have executed such agreements with all parties who may have helped to develop our intellectual property or had access to our proprietary information, nor that our agreements will not be breached. We cannot guarantee that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the EU or the U.S. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S. and elsewhere. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or maintain a competitive advantage in our market, which could materially and adversely affect our business, results of operations and financial condition.

Any disclosure to or misappropriation by third parties of our confidential proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market.

**Changes in patent law could diminish the value of patents in general, thereby impairing our ability to protect LiProSal<sup>TM</sup> and CAO22W.**

As is the case with other biopharmaceutical companies, our success will be heavily dependent on intellectual property, particularly patents. Obtaining and enforcing patents in the biopharmaceutical industry involves both technological and legal complexity. Therefore, obtaining and enforcing biopharmaceutical patents is costly, time-consuming and inherently uncertain. In addition, the U.S. has recently enacted and is currently implementing wide-ranging patent reform legislation. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in other situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U.S. Congress, the federal courts, and the U.S. PTO, the laws and regulations governing patents could change in ways that would weaken our ability to obtain patents and to enforce patents that we might obtain in the future. Similarly, changes in EU patent law and elsewhere could negatively affect the value of our patents registered outside of the U.S.

**Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with any of these requirements.**

The U.S. PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent process. There are situations in which noncompliance can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case, which could have a material adverse effect on our business, results of operations and financial condition.

**We may not be able to protect our intellectual property rights throughout the world.**

Filing, prosecuting and defending patents on LiProSal<sup>TM</sup>, CAO22W and any future product candidates throughout the world is prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. These products may compete with our products in jurisdictions where we do not have any issued or licensed patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

## Item 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

*You should read the following discussion and analysis of our financial condition and results of our operations together with our financial statements and the notes thereto appearing elsewhere in this Annual Report. This discussion contains forward-looking statements reflecting our current expectations, whose actual outcomes involve risks and uncertainties. Actual results and the timing of events may differ materially from those stated in or implied by these forward-looking statements due to a number of factors, including those discussed in the sections entitled "Risk Factors," "Cautionary Statement regarding Forward-Looking Statements" and elsewhere in this Annual Report. Please see the notes to our Financial Statements for information about our Significant Accounting Policies and Recent Accounting Pronouncements.*

### Overview

Alzamend Neuro<sup>TM</sup> is a company focused on the facilitation of bringing technologies to market which help with the treatment, prevention or cure of Alzheimer's Disease.

On May 1, 2016, we obtained a royalty-bearing, exclusive worldwide license from the University, to a mutant-peptide immunotherapy that is designed to be used both as a vaccine and prophylactic against Alzheimer's. This peptide, known as CAO22W, has transitioned from early stage development to an extensive program of preclinical study and evaluation with an anticipated completion date at the end of May 2019. CAO22W will require extensive clinical evaluation, regulatory review and approval, significant marketing efforts and substantial investment before it can provide us with any revenue. We plan to file an IND with the FDA with respect to CAO22W in the second quarter of 2019 and prepare to conduct a Phase 1 Clinical Trial at Emory University Alzheimer's Disease Research Center starting in the latter half of 2019. Upon FDA approval of the IND, we plan to work with Dr. Chuanhai Cao, who is associated with the College of Chemistry, a neuroscientist at the University of South Florida Health Byrd Alzheimer's Institute and the inventor of CAO22W, and Dr. Cao's medical and biotech research team to launch our Phase 1 Clinical Trial with up to 30 human patients.

### Recent Developments

On July 2, 2018, we obtained two royalty-bearing, exclusive worldwide licenses from the University, to a therapy known as LiProSal<sup>TM</sup> to mitigate extreme agitation and forestall other deterioration as displayed by patients with up to moderate AD. LiProSal<sup>TM</sup> is an ionic cocrystal of lithium for the treatment of Alzheimer's and possibly other neurodegenerative diseases. Recent evidence suggests that lithium may be efficacious for both the treatment and prevention of AD. Unlike traditional medications, which only address a single therapeutic target, lithium appears to be neuroprotective through several modes of action. For example, it exerts neuroprotective effects, in part, by increasing the brain-derived neurotrophic factor leading to restoration of learning and memory based on the results with some of the animal subjects during the preclinical studies. Another neuroprotective mechanism of lithium is attenuation of the production of inflammatory cytokines like IL-6 and nitric oxide in activated microglia. Alzamend is continuing to work with two of the inventors of this therapeutic, both at the USF Morsani College of Medicine; Jun Tan, PhD, MD, Professor at the College of Medicine Neurosurgery, Endowed Chair, College of Medicine Psychiatry and Behavioral Neurosciences and the Silver Endowed Chair in Developmental Neurobiology, Department of Psychiatry & Behavioral Medicine and Roland D. Shytle, PhD, Associate Professor, Center of Excellence for Aging & Brain Repair. Dr. Tan and Dr. Shytle with Adam J. Smith, PhD., MSBE, Michael Zaworotko, PhD., and Naga Duggirala, PhD., all formerly with the University of South Florida, have designed, synthesized and characterized this ionic cocrystal of lithium, which Alzamend has named LiProSal. LiProSal<sup>TM</sup> has been shown to exhibit improved pharmacokinetics compared to current FDA-approved lithium-based drugs as well as bioactive in many in vitro models of Alzheimer's disease. LiProSal<sup>TM</sup> may prove to be a major improvement over current lithium-based treatments and may also represent a means of treating AD.

On May 29, 2018, the Company implemented a 1-for-4 Reverse Stock Split of its Common Stock. The Reverse Stock Split became effective on December 13, 2018. As a result of the Reverse Stock Split, every four (4) shares of the Company's pre-Reverse Stock Split Common Stock were combined and reclassified into one share of the Company's Common Stock. The number of shares of Common Stock subject to outstanding options and warrants were also reduced by a factor of four as of December 13, 2018. All historical share and per-share amounts reflected throughout the consolidated financial statements and other financial information in this filing have been adjusted to reflect the Reverse Stock Split. The par value per share of the Company's Common Stock was not affected by the Reverse Stock Split.



**RESULTS OF OPERATIONS FOR THE YEARS ENDED APRIL 30, 2018 AND 2017**

The following table summarizes the results of our operations for the years ended April 30, 2018 and 2017.

**ALZAMEND NEURO, INC.**  
**Condensed Statements of Operations**

	<b>For the Year Ended April 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>OPERATING EXPENSES</b>		
Research and development	\$ 323,403	\$ 275,047
General and administrative	575,027	1,273,350
Total operating expenses	<u>898,430</u>	<u>1,548,397</u>
<b>Loss from operations</b>	(898,430)	(1,548,397)
<b>OTHER EXPENSE, NET</b>		
Interest income - related party	7,341	-
Interest expense	(30,259)	(11,390)
Interest expense - debt discount	<u>(10,315)</u>	<u>(10,111)</u>
<b>Total other expense, net</b>	(33,233)	(21,501)
<b>NET LOSS</b>	<u>\$ (931,663)</u>	<u>\$ (1,569,898)</u>
<b>Basic and diluted net loss per common share</b>	<u>\$ (0.02)</u>	<u>\$ (0.05)</u>
<b>Basic and diluted weighted average common shares outstanding</b>	<u>37,889,196</u>	<u>28,801,309</u>

**Revenue**

Alzamend Neuro, Inc. is a development stage company that was formed on February 26, 2016. The Company was formed to acquire and commercialize patented intellectual property and know how to prevent, treat and cure the crippling and deadly disease, Alzheimer's. At that time, Alzamend had only one product candidate, CAO22W, which is a mutant-peptide immunotherapy that is designed to be used both as a vaccine and prophylactic against Alzheimer's. CAO22W is beginning to complete its preclinical stage of development and will require extensive clinical study, review and evaluation, regulatory review and approval, significant marketing efforts and substantial investment before CAO22W and any successors could provide us with any revenue. The Company did not generate any revenues during the years ended April 30, 2018 and 2017, and we do not anticipate that we will generate revenue for the foreseeable future.

## General and administrative expenses

General and administrative expenses for the years ending April 30, 2018 and 2017 were \$575,027 and \$1,273,350, respectively. As reflected in the table below, general and administrative expenses primarily consisted of the following expense categories: management services, professional fees, and advertising and promotion. The remaining general and administrative expenses of \$55,298 and \$109,636, respectively, primarily consisted of payments for transfer agent fees, travel, and other office expenses, none of which is significant individually.

	For the Year Ended April 30,	
	2018	2017
Management Services	\$ 240,000	\$ 420,000
Professional fees	249,820	412,875
Advertising and promotion	29,909	330,839
Other general and administrative expenses	55,298	109,636
Total general and administrative expenses	<u>\$ 575,027</u>	<u>\$ 1,273,350</u>

### Management services

The Company had no full-time employees during the years ended April 30, 2018 and 2017. The services of the two officers and Executive Chairman of the Company are provided pursuant to the terms of an MSA entered into with Avalanche, a related party, on May 1, 2016. Avalanche provides management, consulting and financial services to the Company. Such services include advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorney, financial advisors and other professionals. The term of the MSA, as amended, is for the period May 1, 2016 to December 31, 2017 and was extended by written agreement. The Company initially paid \$40,000 per month for these services and, beginning February 2017, began paying \$20,000 per month. During the years ended April 30, 2018 and 2017, the Company recognized \$240,000 and \$420,000, respectively, in management fees. At April 30, 2018 and April 30, 2017, \$3,000 and \$180,000, respectively, was included within related party payable on the Company's balance sheet. The MSA was terminated as of December 31, 2018.

### Professional fees

The second largest component of our general and administrative expenses is professional fees. During the years ended April 30, 2018 and 2017, the Company reported professional fees of \$249,820 and \$412,875, respectively, which are principally comprised of the following items:

#### Year Ended April 30, 2018

- During the year ended April 30, 2018, the Company incurred \$82,202 in audit fees.
- During January 2017, the Company entered into consulting agreements with two consultants. Both consulting agreements had a term of one year and provided for aggregate compensation of \$50,000. The consulting services included assistance in evaluating strategic opportunities, business advice and services related to sales, marketing, investor relation and other incidental services on behalf of the Company. During the year ended April 30, 2018, the Company recorded an expense of \$35,617 as a result of these two consulting agreements.
- The Company entered into a five year consulting agreement with Spartan pursuant to which Spartan has agreed to provide consulting services with respect to general corporate matters, including, but not limited to, advice and input with respect to raising capital, potential merger and acquisition transactions, identifying suitable personnel for management, developing corporate structure and finance strategies, assisting the Company with strategic introductions, assisting management with enhancing corporate and shareholder value and introducing the Company to potential investors. In December 2017, since the maximum amount was raised in a prior private placement, the Company paid to Spartan a consulting fee of \$1,400,000 for the services to be rendered over the sixty (60) month term of this consulting agreement. During the year ended April 30, 2018, the Company recorded an expense of \$93,333 as a result of this consulting agreement.

#### *Year Ended April 30, 2017*

- During the year ended April 30, 2017, as a result of a consulting agreement with Hallmark Investments, LLC (***Hallmark***), the Company incurred \$120,000 in professional fees. Effective May 1, 2016, the Company entered into a one-year Consulting Agreement with Hallmark. The terms of the Consulting Agreement provided for \$120,000 in payments to Hallmark for strategic advisory services related to the operations of the Company.
- During the year ended April 30, 2017, the Company incurred \$72,985 for information technology and website development services from two vendors.
- During the year ended April 30, 2017, the Company incurred \$76,625 in audit and legal fees related to the Company's annual audit of its financial statements for the year ended April 30, 2016, audit related fees attributed to the filing of the Company's Prior Offering Statement and legal fees resulting from work on the Company's various regulatory and financing matters.
- The Company incurred \$57,447 in stock-based compensation expense from the issuance of 337,500 shares of Common Stock to consultants for sales, marketing, investor relation and other incidental services.
- The remaining amounts attributed to professional fees incurred by the Company during the year ended April 30, 2017 are attributed to various types of professional fees, such as FDA consulting services, none of which is significant individually.

#### *Advertising and promotion*

During the years ended April 30, 2018 and 2017, the Company incurred \$29,909 and \$330,839, respectively, in advertising and promotion related expenses. The majority of these expenditures were related to direct advertising of the Company's Offering Statement on Google and Facebook, the development of a social media strategy, costs associated with an inbound call center and the development of videos to convey the Company's mission.

#### **Research and development expenses**

Research and development expenses for the years ending April 30, 2018 and 2017 were \$323,403 and \$275,047, respectively. As reflected in the table below, research and development expenses primarily consisted of professional fees as well as licenses and fees.

	<b>For the Year Ended April 30,</b>	
	<b>2018</b>	<b>2017</b>
Professional fees	\$ 101,277	\$ 5,882
Licenses and fees	219,163	269,165
Other research and development expenses	2,963	-
Total research and development expenses	<u>\$ 323,403</u>	<u>\$ 275,047</u>

#### *Professional fees*

The largest component of our research and development expenses is professional fees. During the years ended April 30, 2018 and 2017, the Company reported professional fees of \$101,277 and \$5,882, respectively, which are principally comprised of professional fees incurred by the Company during the year ended April 30, 2018 are attributed to various types of scientific services, including FDA consulting services.

### *Licenses and fees*

There are certain initial license fees and milestone payments required to be paid to the University of South Florida and the USF Health Byrd Alzheimer's Institute, a multi-disciplinary center at the University of South Florida, for the licenses of the Technologies, pursuant to the terms of the License Agreement with the Licensor and a direct support organization of the University.

The License Agreement for CAO22W requires, in addition to royalty payments of 4% on net sales of products developed from the licensed technology, the Company to pay a license fee of \$100,000 on June 25, 2016 and December 31, 2016. As an additional licensing fee, Licensor is entitled to receive that number of shares of the Company's Common Stock equal to five percent (5%) of the total number of issued and outstanding shares outstanding on May 1, 2016, subject to additional issuances until such time as the Company has received a total of \$5 million in cash in exchange for the Company's equity securities. Additionally, the Company is required to pay milestone payments to Licensor for the license of the technology.

During the years ended April 30, 2018 and 2017, the Company incurred \$218,416 and \$56,962, respectively, in non-cash charges from issuances of Common Stock to the Licensor.

### ***Other (expense) income, net***

During the year ended April 30, 2018, the Company reported other expense of \$33,233. Other expense includes interest expense of \$30,259 and amortization of original issue discounts on notes payable and notes payable, related parties of \$10,315, partially offset by \$7,341 of interest income, related parties.

During the year ended April 30, 2017, the Company reported other expense of \$21,501. Other expense includes interest expense of \$11,390 and amortization of original issue discounts on notes payable and notes payable to related parties of \$10,111.

At April 30, 2018, the Company had no outstanding borrowings. At April 30, 2017, the aggregate outstanding balance on the Company's borrowings was \$325,211 consisting of notes payable of \$71,382 and notes payable, related parties of \$253,829.

### ***Current and deferred income taxes***

The Company has made the decision to fully reserve its net deferred tax assets. As a result of this decision, the Company did not record an income tax benefit during the year ended April 30, 2018 and 2017.

The ultimate realization of deferred tax assets is dependent upon the existence, or generation, of taxable income in the periods when those temporary differences and net operating loss carryovers are deductible. Management considers the scheduled reversal of deferred tax liabilities, taxes paid in carryover years, projected future taxable income, available tax planning strategies, and other factors in making this assessment. Based on available evidence, management believes it is less likely than not that all of the deferred tax assets will be realized. Accordingly, the Company has established a 100% valuation allowance.

### **LIQUIDITY AND CAPITAL RESOURCES**

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern. As of April 30, 2018, the Company had cash of \$545,001 and an accumulated deficit of \$2,513,137. The Company has incurred recurring losses and reported losses for the year ended April 30, 2018 totaled \$931,663. In the past, the Company has financed its operations principally through issuances of promissory notes and equity securities. During the year ended April 30, 2018, the Company continued to successfully obtain additional equity and debt financing.

The Company expects to continue to incur losses for the foreseeable future and needs to raise additional capital until it is able to generate revenues from operations sufficient to fund its development and commercial operations. Based on our current business plan, we believe that our cash and cash equivalents at April 30, 2018, are not sufficient to meet our anticipated cash requirements during the twelve-month period subsequent to the issuance of the financial statements included in this Annual Report on Form 1-K. Management believes that the Company has access to capital resources through potential public or private issuance of debt or equity securities. However, the Company cannot be certain that additional funding will be available on acceptable terms, or at all, in which case it may have to significantly delay, scale back or discontinue the development and/or commercialization of its product. The Company may also be required to (a) seek collaborators for its product at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (b) relinquish or otherwise dispose of rights to technology or its product that the Company would otherwise seek to deploy or commercialize. These matters raise substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might become necessary should the Company be unable to continue as a going concern.

On April 10, 2018, Avalanche issued a promissory note to the Company (the "**AVLP Note**") to evidence the Company's loan of up to \$995,500 for a period ending on April 30, 2019, subject to the terms and conditions stated in the AVLP Note. The AVLP Note accrues interest at 10% per annum and includes a 10% original issue discount. At April 30, 2018, the Company has provided loans to Avalanche in the principal amount of \$800,000, of which \$400,000 was repaid, resulting in net loans to Avalanche of \$400,000 and an original issue discount of \$40,000.

During January 2017, the Company entered into a promissory note and received net proceeds of \$65,000. As consideration for this loan, the Company issued a promissory note in the aggregate principal amount of \$75,000, which included an OID and fees of \$10,000. This loan was repaid during the year ended April 30, 2018.

At April 30, 2017, the outstanding balance on short term borrowings from Avalanche, a related party, was \$180,100. During the year ended April 30, 2018, Avalanche provided an additional \$123,500 in short term financing. This short-term obligation was non-interest bearing, due upon demand and repaid during the year ended April 30, 2018.

During January 2017, the Company entered a promissory note and received net proceeds of \$70,000 from Gary Gottlieb, a related party. As consideration for this loan, the Company issued a promissory note in the aggregate principal amount of \$80,000, which included an OID of \$10,000. This promissory note accrued interest at 15% per year and during the years ended April 30, 2018 and 2017. The Company repaid this loan during the year ended April 30, 2018.

On October 1, 2017, the Company entered into a promissory note in the principal amount of \$47,520 with DPW Holdings, Inc., a related party ("**DPW**"). The promissory note included an OID of \$3,520 resulting in net proceeds to the Company of \$44,000, yielded 8% simple interest on the principal amount, and was due on August 16, 2018. Prior to April 30, 2018, the Company repaid the outstanding balance to DPW.

Between December 13, 2017 and December 29, 2017, the Company entered into subscription agreements for the purchase of 311.75 units at \$10,000 for each unit purchased. Each unit consisted of 10,000 shares of Common Stock. In aggregate, the 311.75 units represented 3,117,500 shares of Common Stock for an aggregate purchase price of \$3,117,500, or \$1.00 per share, pursuant to the terms of a Private Placement Memorandum dated August 17, 2017 (the "**PPM**"). In conjunction with this PPM, and inclusive of the sale of 107.7 units that occurred on October 19, 2017, the Company incurred \$419,450 in placement fees and \$57,900 in legal and filing fees, resulting in net proceeds to the Company of \$3,717,150.

## CONTRACTUAL OBLIGATIONS

On May 1, 2016, the Company entered into the License Agreement with the Licensor pursuant to which the Licensor granted the Company a royalty bearing, exclusive worldwide license, limited to the field of Alzheimer's Immunotherapy and Diagnostics, under United States Patent No. 8,188,046, entitled "Amyloid Beta Peptides and Methods of Use", filed April 7, 2009 and granted May 29, 2012.

In addition to royalty payments of 4% on net sales of products developed from the licensed technology, the Company was required to pay a license fee of \$100,000 on June 25, 2016 and December 31, 2016. As an additional licensing fee, the Licensors are entitled to receive that number of shares of the Company's Common Stock equal to five percent (5%) of the sum of the total number of issued and outstanding shares plus any securities that are convertible into or exercisable or exchangeable for shares of Common Stock, subject to adjustment for additional issuances until such time as the Company has received a total of \$5 million in cash in exchange for the Company's equity securities. Additionally, the Company is required to pay milestone payments on the due dates to Licensors for the license of the technology, as follows:

Payment	Due Date	Event
\$ 50,000	September 30, 2019	Upon IND application filing
\$ 50,000	12 months from IND application filing date	Upon first dosing of patient in first Phase I Clinical Trial
\$ 175,000	12 months from first patient dosed in Phase I	Upon Completion of first Phase I Clinical Trial
\$ 500,000	24 months from completion of first Phase I Trial	Upon Completion of first Phase II Clinical Trial
\$ 1,000,000	12 months from completion of the first Phase II Clinical Trial	Upon first patient treated in a Phase III Clinical Trial
\$ 10,000,000	7 years from the effective date of the agreement	Upon FDA BLA Approval

None of these milestones was met as of the date of this Annual Report. If we fail to meet a milestone by its specified date, the Licensors may terminate the License Agreement.

Licensors were also granted a preemptive right to acquire such shares or other equity securities that may be issued from time to time by the Company while Licensors remain the owner of any equity securities of the Company. Further, if the Company issues equity securities at a price per share that is less than the price paid by purchasers in a transaction for aggregate consideration of at least \$5,000,000 (the "**Investment Price**"), then the number of shares owned by Licensee shall be increased upon such issuance. The amount of the increase shall be determined by multiplying the number of shares then owned by Licensors by a fraction; the numerator of which shall be equal to the number of shares of Common Stock outstanding immediately after the issuance of additional shares of common stock, and the denominator of which shall be equal to the sum of (i) the number of shares of Common Stock outstanding immediately prior to the issuance of additional shares of Common Stock plus (ii) the number of shares of Common Stock which the aggregate consideration for the total number of additional shares of Common Stock so issued would purchase at the Investment Price.

There are certain license fees and milestone payments required to be paid for the licensing of the LiProSal<sup>TM</sup> technology, pursuant to the terms of the Standard Exclusive License Agreements with Sublicensing Terms, both dated June 21, 2018 (the "**LiProSal<sup>TM</sup> License Agreements**") with the Licensors and the University. In addition, a royalty payment of 3% is required pursuant to License #18110 while License #1811 requires a royalty payment of 1.5% on net sales of products developed from the licensed technology. For the two LiProSal<sup>TM</sup> licenses, in the aggregate, the Company is required to pay initial license fees of \$50,000 no later than July 31, 2018 and \$150,000 no later than October 31, 2018, although the Company is in discussions with the University to defer the payment due date of the initial license fees. As an additional licensing fee, the Licensors are entitled to receive that number of shares of Common Stock equal to three percent (3%) of the sum of the total number of issued and outstanding shares. Additionally, the Company is required to pay milestone payments on the due dates to Licensors for the license of the technology, as follows:

Payment	Due Date	Event
\$ 50,000	November 1, 2019	Pre-IND meeting
\$ 65,000	6 months from IND filing date	IND application filing
\$ 190,000	12 months from IND filing date	Upon first dosing of patient in a clinical trial
\$ 500,000	12 months from first patient dosing	Upon Completion of first clinical trial
\$ 1,250,000	12 months from completion of the first Phase II clinical trial	Upon first patient treated in a Phase III Clinical Trial
\$ 10,000,000	8 years from the Effective Date of the Agreement	Upon FDA Approval

#### Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources that is material to investors.

### Item 3. Directors, Executive Officers and Corporate Governance.

The following table sets forth information regarding our executive officers, directors and significant employees, including their ages as of the date of this Annual Report:

Name	Age	Position
Stephan Jackman	44	Chief Executive Officer
Kenneth S. Cragun	58	Chief Financial Officer
Milton C. Ault, III	49	Executive Chairman & Director
Philip E. Mansour	50	Director
William B. Horne	51	Director

Directors serve until the next annual meeting and until their successors are elected and qualified. Officers are appointed to serve for one year until the meeting of the Board following the annual meeting of stockholders and until their successors have been elected and qualified.

#### Stephan Jackman

Mr. Jackman has played an intricate role in the development of therapeutic treatments, products and programs from the research stage to market and commercialization. He has demonstrated a dedicated dual focus of creating value for internal and external stakeholders while developing strategic alliances and cross-function teams to meet and exceed goals. Mr. Jackman has held positions of increasing responsibility at Novartis Pharmaceuticals Corporation, L'Oréal USA, SBM Management Services, and Family Intervention Services. Prior to joining Alzamend Neuro<sup>TM</sup>, Mr. Jackman was the Chief Operating Officer of Ennaid Therapeutics, an emerging biopharmaceutical focusing on cures for mosquito borne infectious diseases, such as Zika and Dengue viruses. Additionally, he has been an independent project and management consultant assisting start-ups, Fortune 500 companies and non-profits with major strategic initiatives. Mr. Jackman holds a Master's of Science, Management, and a Bachelor's of Engineering, Mechanical Engineering, from Stevens Institute of Technology.

We believe Mr. Jackman is qualified to serve as our Chief Executive Officer because of his extensive leadership experience and industry knowledge.

#### Kenneth S. Cragun

Mr. Cragun served as a CFO Partner at Hardesty, LLC, a national executive services firm since October 2016. His assignments at Hardesty included serving as CFO of CorVel Corporation, a \$1.1 billion market cap publicly traded company (NASDAQ: CRVL) and a nationwide leader in technology driven, healthcare-related, risk management programs and of RISA Tech, Inc. a private structural design and optimization software company. Mr. Cragun was also CFO of two NASDAQ-listed companies, Local Corporation, from April 2009 to September 2016, which operated Local.com, a U.S. top 100 website, and Modtech Holdings, Inc., from June 2006 to March 2009, a supplier of modular buildings. Prior thereto, he had financial leadership roles with increasing responsibilities at MIVA, Inc., ImproveNet, Inc., NetCharge Inc., C-Cube Microsystems, Inc, and 3-Com Corporation. Mr. Cragun is currently the Chief Accounting Officer of DPW Holdings, Inc. and on the Board of Directors and Chairman of the Audit Committee of Verb Technology Company, Inc. (OTC: FUSZD). Mr. Cragun began his professional career at Deloitte. Mr. Cragun holds a Bachelor of Science degree in accounting from Colorado State University-Pueblo.

Mr. Cragun's industry experience is vast with extensive experience in fast-growth environments and building teams in more than 20 countries. Mr. Cragun has led multiple financing transactions, including IPOs, PIPEs, convertible debt, term loans, and lines of credit. For these reasons, we believe that he is well qualified to service as the Company's CFO.

#### Philip E. Mansour

Since October 2008, Mr. Mansour has been the full-time principal of PMC Solutions, LLC, specializing in consulting to companies on issues of operational management, strategic planning, marketing business development and disruptive technology. Additionally, Mr. Mansour has provided executive coaching services. Mr. Mansour has served as a director and as the President and Chief Executive Officer of Avalanche since May 2014. Mr. Mansour worked as the Chief Operational Officer with the RXtra Solutions organization. The organization was a privately-owned set of health care development companies which had footprints in the compounding pharmacy, diagnostics, medical equipment, chemical distribution and wellness provider spaces. Vice President, corporate development for Conceivex, Inc., a private company focused on At-Home Infertility treatment. His prior experience includes leading the research and development for some prominent educational technology companies for more than 2 decades and leading multi-million-dollar government grants with leading universities. His entrepreneurial and significant corporate experience is expected to benefit the Company. We believe that Mr. Mansour's business background demonstrates he has the qualifications to serve as one of our directors.

**Milton C. Ault, III**

Mr. Ault founded Alzamend Neuro, Inc., a biotechnology firm dedicated to finding the treatment, prevention and cure for Alzheimer's Disease on February 25, 2016 and has served as its Executive Chairman since November 2, 2018 and as its Chairman since inception.

Mr. Ault is a seasoned business professional and entrepreneur who has spent more than twenty-seven years identifying value in various financial markets including equities, fixed income, commodities, and real estate. On March 16, 2017, Mr. Ault was appointed Executive Chairman of the Board for DPW Holdings, Inc. ( "**DPW**" ), formerly known as Digital Power Corporation (NYSE: DPW) and on December 28, 2017, Mr. Ault was appointed Chief Executive Officer of DPW. Mr. Ault has served as Chairman of Ault & Company, a holding company since December 2015, and as Chairman of Avalanche, a publicly traded company, since September 2014. Since January 2011, Mr. Ault has been the Vice President of Business Development for MCKEA Holdings, LLC, a family office. Mr. Ault has consulted for a few publicly traded and privately held companies, which range from development stage to seasoned businesses, providing each of them the benefit of his diversified experience.

We believe that Mr. Ault's business background demonstrates he has the qualifications to serve as one of our directors and as Chairman.

**William B. Horne.**

Mr. Horne has served as director for Alzamend Neuro<sup>TM</sup> since June 01, 2016. Mr. Horne served as the Chief Financial Officer from June 2016 through December 2018. Mr. Horne is a member of the board of directors of DPW since October 2016. On January 25, 2018, Mr. Horne was appointed as DPW's Chief Financial Officer. Mr. Horne is a director of and Chief Financial Officer of Avalanche, a publicly traded company. He has served as the Chief Financial Officer of Targeted Medical Pharma, Inc. (OTCBB: TRGM) since August 2013.

Mr. Horne previously held the position of Chief Financial Officer in various companies in the healthcare and high-tech field, including OptimisCorp, from January 2008 to May 2013, a privately held, diversified healthcare technology company located in Los Angeles, California.

Mr. Horne served as the Chief Financial Officer of Patient Safety Technologies, Inc. (OTCBB: PSTX), a medical device company located in Irvine, California, from June 2005 to October 2008 and as the interim Chief Executive Officer from January 2007 to April 2008. In his dual role at Patient Safety Technologies, Mr. Horne was directly responsible for structuring the divestiture of non-core assets, capital financings and debt restructuring.

Mr. Horne has also held supervisory positions at Price Waterhouse, LLP and has a Bachelor of Arts Magna Cum Laude in Accounting from Seattle University.

We believe that Mr. Horne's extensive financial and accounting experience in diversified industries and with companies involving complex transactions give him the qualifications and skills to serve as one of our directors.

**Board Leadership Structure and Risk Oversight**

The Board oversees our business and considers the risks associated with our business strategy and decisions. The Board currently implements its risk oversight function as a whole. On November 2, 2018, the Board adopted a charter that establishes an Audit Committee and a Nomination & Governance Committee. Each of the Board committees will provide risk oversight in respect of its areas of concentration and reports material risks to the board for further consideration.

**Term of Office**

Directors serve until the next annual meeting and until their successors are elected and qualified. Officers are appointed to serve for one year until the meeting of the Board following the annual meeting of stockholders and until their successors have been elected and qualified.



## Director Independence

We use the definition of “independence” of The NASDAQ Stock Market to make this determination. NASDAQ Listing Rule 5605(a)(2) provides that an “independent director” is a person other than an officer or employee of the company or any other individual having a relationship which, in the opinion of the Company’s Board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. The NASDAQ listing rules provide that a director cannot be considered independent if:

- the director is, or at any time during the past three years was, an employee of the company;
- the director or a family member of the director accepted any compensation from the company in excess of \$120,000 during any period of 12 consecutive months within the three years preceding the independence determination (subject to certain exemptions, including, among other things, compensation for board or board committee service);
- the director or a family member of the director is a partner in, controlling stockholder of, or an executive officer of an entity to which the company made, or from which the company received, payments in the current or any of the past three fiscal years that exceed 5% of the recipient’s consolidated gross revenue for that year or \$200,000, whichever is greater (subject to certain exemptions);
- the director or a family member of the director is employed as an executive officer of an entity where, at any time during the past three years, any of the executive officers of the company served on the compensation committee of such other entity; or
- the director or a family member of the director is a current partner of the company’s outside auditor, or at any time during the past three years was a partner or employee of the company’s outside auditor, and who worked on the company’s audit.

Under such definitions, we have no independent directors. However, our Common Stock is not currently quoted or listed on any national exchange or interdealer quotation system with a requirement that a majority of our Board be independent and, therefore, the Company is not subject to any director independence requirements.

## Family Relationships

There are no family relationships among any of our officers or directors.

## Involvement in Certain Legal Proceedings

Except as disclosed below, to our knowledge, none of our current directors or executive officers has, during the past ten years:

- been convicted in a criminal proceeding or been subject to a pending criminal proceeding (excluding traffic violations and other minor offenses);
- had any bankruptcy petition filed by or against the business or property of the person, or of any partnership, corporation or business association of which he was a general partner or executive officer, either at the time of the bankruptcy filing or within two years prior to that time;
- been subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction or federal or state authority, permanently or temporarily enjoining, barring, suspending or otherwise limiting, his involvement in any type of business, securities, futures, commodities, investment, banking, savings and loan, or insurance activities, or to be associated with persons engaged in any such activity;
- been found by a court of competent jurisdiction in a civil action or by the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated;

- been the subject of, or a party to, any federal or state judicial or administrative order, judgment, decree, or finding, not subsequently reversed, suspended or vacated (not including any settlement of a civil proceeding among private litigants), relating to an alleged violation of any federal or state securities or commodities law or regulation, any law or regulation respecting financial institutions or insurance companies including, but not limited to, a temporary or permanent injunction, order of disgorgement or restitution, civil money penalty or temporary or permanent cease-and-desist order, or removal or prohibition order, or any law or regulation prohibiting mail or wire fraud or fraud in connection with any business entity; or
  - been the subject of, or a party to, any sanction or order, not subsequently reversed, suspended or vacated, of any self-regulatory organization (as defined in Section 3(a)(26) of the Exchange Act), any registered entity (as defined in Section 1(a)(29) of the Commodity Exchange Act), or any equivalent exchange, association, entity or organization that has disciplinary authority over its members or persons associated with a member.
1. Mr. Ault held series 7, 24, and 63 licenses and managed four domestic hedge funds and one bond fund from 1998 through 2008. On April 26, 2012, as a result of an investigation by FINRA involving activities during 2008, Mr. Ault agreed to a settlement with FINRA in which he did not admit to any liability or violation of any laws or regulatory rules and that included restitution and a suspension from association with a FINRA member firm for a period of 2 years. As part of that settlement, Mr. Ault agreed that he would make restitution to certain investors. Mr. Ault did not within the prescribed time period make a restitution payment to certain of the investors as he was unable to locate all of them, nor did he forward the undistributed restitution in the state where the investor was known to have resided, as directed by FINRA.
  2. Mr. Ault was CEO, President and Chairman of Zealous Holdings, Inc. that filed for bankruptcy protection under Chapter 11 of Title 11 of the United States Code (the “Bankruptcy Code”) on February 20, 2009, in the U.S. Bankruptcy Court, Central District of California. This Chapter 11 filing was subsequently converted to a Chapter 7 filing by order of the Bankruptcy Court. Zealous Holdings, Inc. was not an entity that was entitled to a discharge under the bankruptcy code. As such Zealous Holdings, Inc. did not receive a discharge. Ultimately, Zealous Holdings, Inc. ceased doing business and was permanently closed.
  3. Mr. Ault filed for bankruptcy protection under the Bankruptcy Code on December 8, 2009, in the U.S. Bankruptcy Court, Central District of California. This Chapter 13 filing was subsequently converted to a Chapter 7 filing by order of the Bankruptcy Court and months later, the petition being withdrawn and dismissed without prejudice.
  4. Mr. Cragun served as Chief Financial Officer of Local Corporation (April 2009 to September 2016), formerly based in Irvine, California, and, in June 2015, Local Corporation filed a voluntary petition in the United States Bankruptcy Court for the Central District of California seeking relief under the provisions of Chapter 11 the Bankruptcy Code.
  5. Mr. Cragun served as Chief Financial Officer of Modtech Holdings, Inc. (June 2006 to March 2009), formerly based in Perris, California and, in October 2008, Modtech Holdings, Inc. filed a voluntary petition in the United States Bankruptcy Court for the Central District of California seeking relief under the provisions of Chapter 11 of the Bankruptcy Code.

Except as set forth in our discussion below in “Certain Relationships and Related Transactions,” none of our directors or executive officers has been involved in any transactions with us or any of our directors, executive officers, affiliates or associates which are required to be disclosed pursuant to the rules and regulations of the SEC.

We are not currently a party to any legal proceedings, the adverse outcome of which, individually or in the aggregate, we believe will have a material adverse effect on our business, financial condition or operating results.

#### **Code of Business Conduct and Ethics**

Our Board has adopted a written code of business conduct and ethics, revised effective May 29, 2018, that applies to our directors, officers and employees, including our principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. We have posted on our website a current copy of the code and all disclosures that are required by law in regard to any amendments to, or waivers from, any provision of the code.

## EXECUTIVE COMPENSATION

The following table represents information, as of October 31, 2018, regarding the total compensation of our executive officers and director of the Company since inception:

Name and Principal Position	Cash Compensation (\$)	Other Compensation (\$)(1)	Total Compensation (\$)
Philip E. Mansour, President, Chief Executive Officer & Director	—	600	600
Milton C. Ault, III, Executive Chairman & Director	—	600	600
William B. Horne, Chief Financial Officer & Director	—	600	600

(1) The values reported in the “Other Compensation” column represents the aggregate grant date fair value, computed in accordance with Accounting Standards Codification (“ASC”) 718 Share Based Payments, of grants of stock options to each of our named executive officers and directors.

No compensation was paid to the officers and directors identified above outside of the MSA with Avalanche. The services of the two officers and Executive Chairman of the Company were provided pursuant to the terms of an MSA entered into with Avalanche, a related party, on May 1, 2016. Pursuant to the terms of the MSA, Avalanche provided management, consulting and financial services to Alzamend. Such services included advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorney, financial advisors and other professionals. The term of the MSA, as amended, was for the period May 1, 2016 to December 31, 2017 and was extended by written agreement. The Company initially paid \$40,000 per month for these services and, beginning February 2017, began paying \$20,000 per month. During the years ended April 30, 2018 and 2017, the Company recorded \$240,000 and \$420,000, respectively, in management fees. At April 30, 2018 and April 30, 2017, \$3,000 and \$180,000, respectively, was included within related party payable on the Company’s balance sheet.

### Item 4. Security Ownership of Management and Certain Securityholders

The following table shows the beneficial ownership of our Common Stock as of February 15, 2019 held by (i) each person known to us to be the beneficial owner of more than five percent (5%) of any class of our shares; (ii) each director; (iii) each executive officer; and (iv) all directors and executive officers as a group. As of February 15, 2019, there were 51,721,119 shares of Common Stock issued and outstanding and 750,000 shares of Series A Preferred Stock issued and outstanding.

Beneficial ownership is determined in accordance with the rules of the Commission, and generally includes voting power and/or investment power with respect to the securities held. Shares of Common Stock subject to options and warrants currently exercisable or which may become exercisable within 60 days of the date of this Annual Report, are deemed outstanding and beneficially owned by the person holding such options or warrants for purposes of computing the number of shares and percentage beneficially owned by such person, but are not deemed outstanding for purposes of computing the percentage beneficially owned by any other person. Except as indicated in the footnotes to this table, the persons or entities named have sole voting and investment power with respect to all shares of Common Stock shown as beneficially owned by them.

The percentages below are based on fully diluted shares of our Common Stock as of October 31, 2018. Unless otherwise indicated, the principal address of each of the persons below is c/o Alzamend Neuro, Inc., 3802 Spectrum Blvd., Suite #112C, Tampa, FL 33612.

	<b><u>Number of shares of Common Stock Beneficially Owned</u></b>	<b><u>Percentage of Shares Beneficially Owned</u></b>
<b><u>Directors and Officers:</u></b>		
Phil Mansour (1)	2,500,000	3.09%
Milton C. Ault, III (2)(3)	40,000,000	49.45%
William B. Horne (1)	2,500,000	3.09%
All directors and named executive officers as a group (3 persons)	22,500,000	55.63%
<b><u>Greater than 5% Beneficial Owners:</u></b>		
MCKEA Holdings, LLC (4)	37,500,000	46.36%
Congregation Chazon Avrohom (5)	5,902,735	7.30%
University of South Florida (6)	4,208,920	5.20%
Spartan Capital Securities, LLC (7)	4,050,000	5.01%

(1) Consists of options to purchase 2,500,000 shares of Common Stock.

(2) Includes options to purchase 2,500,000 shares of Common Stock.

(3) Consists of MCKEA Holdings' 750,000 Series A Preferred Shares that are convertible into 15,000,000 shares of Common Stock but carry the voting power of 37,500,000 shares of Common Stock.

(4) Consists of 750,000 Series A Preferred Shares that are convertible into 15,000,000 shares of Common Stock but carry the voting power of 37,500,000 shares of Common Stock. The control person of MCKEA Holdings, LLC is Kristine L. Ault, Managing Member, the wife of Mr. Ault, the Executive Chairman of the Company.

(5) The control person of the Congregation Chazon Avrohom is Abraham Biderman.

(6) The control person of the University of South Florida is Theile Riordan.

(7) The control person of Spartan Capital Securities, LLC is John Lowry.

#### **Item 5. Interest of Management and Others in Certain Transactions**

##### **CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS**

###### **Transactions with Related Persons**

As of April 30, 2016, the Company had sold 1,000,000 shares of Series A Convertible Preferred Stock to MCKEA Holdings, LLC ("MCKEA"), a related party. The Series A Convertible Preferred Stock is convertible at a rate of 20:1 into shares of the Company's Common Stock yet carry the voting power on a convertible basis at a rate of 50:1. Kristine L. Ault is the managing member of MCKEA Holdings, LLC and is the wife of Milton C. Ault, III, Chairman of the Company's Board.

On May 1, 2016, the Company entered into an MSA with Avalanche, a related party. Messrs. Ault, Horne and Mansour are also officers and directors of Avalanche. Further, MCKEA is the majority member of Philou Ventures, LLC, which is the controlling shareholder of Avalanche. Pursuant to the terms of the MSA, Avalanche provided management, consulting and financial services to Alzamend. Such services included advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorney, financial advisors and other professionals. The term of the MSA, as amended, was for the period May 1, 2016 to December 31, 2017 and was extended by written agreement. The Company initially paid \$40,000 per month for these services and, beginning February 2017, began paying \$20,000 per month. During the years ended April 30, 2018 and 2017, the Company recognized \$240,000 and \$420,000, respectively, in management fees. At April 30, 2018 and April 30, 2017, \$0 and \$180,000, respectively, was included within related party payable on the Company's balance sheet. The MSA was terminated on December 31, 2018.

On June 28, 2017, MCKEA and Spartan Capital Securities, LLC (“*Spartan*”) entered into a five-year consulting agreement (the “*MCKEA Consulting Agreement*”). Pursuant to the MCKEA Consulting Agreement, upon the receipt by the Company of no less than \$2,500,000 in gross proceeds from a Private Placement Memorandum dated August 17, 2017, MCKEA transferred to Spartan 5,000,000 shares of Alzamend Common Stock. During the term of the MCKEA Consulting Agreement, Spartan will provide consulting services related to general corporate and other matters related to MCKEA’s investment in the Company such as advice on mergers and acquisition transactions, finance strategies, identification of potential management candidates and other strategic introductions.

The amount due at April 30, 2018 and 2017 to MCKEA and the Company’s officers for reimbursement of expenses paid and incurred by these related parties was \$6,636 and \$58,373, respectively. The amounts are included within related party payable on the Company’s balance sheet.

There were no amounts due at April 30, 2018 to related parties from short-term loans. The amount due at April 30, 2017 to related parties from short-term loans, inclusive of unamortized original discount of \$6,271, was \$253,829. The amount is included within notes payable, related parties, on the Company’s balance sheet (See Note 11).

On April 10, 2018, Avalanche, issued the AVL Note to evidence the Company’s loan of up to \$995,500 for the period ending on April 30, 2019, subject to the terms and conditions stated in the AVL Note. The AVL Note accrues interest at 10% per annum and includes a 10% original issue discount. During the six months ended October 31, 2018, the Company provided loans to Avalanche in the principal amount of \$558,000, of which \$386,000 was repaid. As of October 31, 2018, the balance of the loan due to Alzamend is \$570,083.

To the best of our knowledge, from inception to our most recent fiscal year end on April 30, 2018, other than as set forth above, there were no material transactions, or series of similar transactions, or any currently proposed transactions, or series of similar transactions, to which we were or are to be a party, in which the amount involved exceeds \$120,000, and in which any director or executive officer, or any security holder who is known by us to own of record or beneficially own more than 5% of any class of our Common Stock, or any member of the immediate family of any of the foregoing persons, has an interest (other than compensation to our officers and directors in the ordinary course of business).

#### **Item 6. Other Information**

None.

#### **Item 7. Financial Statements**

The financial statements required by this Item 7 are included in this Annual Report on the following page.

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**ALZAMEND NEURO, INC.**

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## REPORT OF INDEPENDENT REGISTERED ACCOUNTING FIRM

To the Board of Directors and Stockholders of Alzamend Neuro, Inc.

### Opinion on the Financial Statements

We have audited the accompanying balance sheet of Alzamend Neuro, Inc. (the "Company") as of April 30, 2018, and the related statement of operations, changes in stockholders' equity (deficit) and cash flows for the year then ended and the related notes to the financial statements (collectively, the financial statements). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company at April 30, 2018, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

### Going Concern Uncertainty

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has a history of significant recurring losses from operations through April 30, 2018, and does not have sufficient working capital at April 30, 2018 to fund its planned operations during the twelve-month period subsequent to the issuance of these financial statements. This raises substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters also are described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

### Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audit included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audit also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audit provide a reasonable basis for our opinion.

/s/ **SQUAR MILNER LLP**

We have served as the Company's auditor since 2019.

San Diego, California  
February 21, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders  
of Alzamend Neuro, Inc.

We have audited the accompanying balance sheet of Alzamend Neuro, Inc. (the “Company”) as of April 30, 2017, and the related statements of operations, changes in stockholders’ deficit and cash flows for the year then ended. These financial statements are the responsibility of the Company’s management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company’s internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Alzamend Neuro, Inc., as of April 30, 2017, and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ Marcum llp

New York, NY

January 29, 2018, except for the reverse stock split disclosed in Note 1, which is dated February 21, 2019



**ALZAMEND NEURO, INC.**  
**Balance Sheets**

	<u>April 30, 2018</u>	<u>April 30, 2017</u>
<b>ASSETS</b>		
<b>CURRENT ASSETS</b>		
Cash	\$ 545,001	\$ 4,976
Note receivable, related party, net	403,333	-
Prepaid expenses and other current assets	1,467,685	52,317
<b>TOTAL CURRENT ASSETS</b>	<u>2,416,019</u>	<u>57,293</u>
Deferred offering cost	-	75,000
<b>TOTAL LONG TERM ASSETS</b>	<u>-</u>	<u>75,000</u>
<b>TOTAL ASSETS</b>	<u>\$ 2,416,019</u>	<u>\$ 132,293</u>
<b>LIABILITIES AND STOCKHOLDERS' DEFICIT</b>		
<b>CURRENT LIABILITIES</b>		
Accounts payable and accrued liabilities	\$ 90,088	\$ 125,965
Related party payable	6,636	266,047
Notes payable, net of discount of \$0 and \$3,618, respectively	-	71,382
Notes payable, related party, net of discount of \$5,857 and \$6,271, respectively	-	253,829
<b>TOTAL CURRENT LIABILITIES</b>	<u>96,724</u>	<u>717,223</u>
<b>COMMITMENTS AND CONTINGENCIES</b>		
<b>STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Convertible Preferred stock, \$0.0001 par value: 10,000,000 shares authorized; Series A Preferred Stock, \$0.0001 stated value per share, 1,360,000 shares designated; 750,000 and 1,360,000 shares issued and outstanding as of April 30, 2018 and 2017, respectively	75	136
Common stock, \$0.0001 par value: 300,000,000 shares authorized; 49,493,196 and 32,874,342 shares issued and outstanding as of April 30, 2018 and April 30, 2017, respectively	4,949	3,287
Additional paid-in capital	4,827,408	993,121
Accumulated deficit	(2,513,137)	(1,581,474)
<b>TOTAL STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u>2,319,295</u>	<u>(584,930)</u>
<b>TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)</b>	<u>\$ 2,416,019</u>	<u>\$ 132,293</u>

The accompanying notes are an integral part of these financial statements.

**ALZAMEND NEURO, INC.**  
**Statements of Operations**

	<b>For the Year Ended April 30,</b>	
	<b>2018</b>	<b>2017</b>
<b>OPERATING EXPENSES</b>		
Research and development	\$ 323,403	\$ 275,047
General and administrative	575,027	1,273,350
Total operating expenses	898,430	1,548,397
<b>Loss from operations</b>	(898,430)	(1,548,397)
<b>OTHER EXPENSE, NET</b>		
Interest income - related party	7,341	-
Interest expense	(30,259)	(11,390)
Interest expense - debt discount	(10,315)	(10,111)
<b>Total other expense, net</b>	(33,233)	(21,501)
<b>NET LOSS</b>	<b>\$ (931,663)</b>	<b>\$ (1,569,898)</b>
<b>Basic and diluted net loss per common share</b>	<b>\$ (0.02)</b>	<b>\$ (0.05)</b>
<b>Basic and diluted weighted average common shares outstanding</b>	<b>37,889,196</b>	<b>28,801,309</b>

The accompanying notes are an integral part of these financial statements.

**ALZAMEND NEURO, INC.**  
**Statements of Cash Flows**

	<b>For the Year Ended April 30,</b>	
	<b>2018</b>	<b>2017</b>
Cash flows from operating activities:		
Net loss	\$ (931,663)	\$ (1,569,898)
Adjustments to reconcile net loss to net cash used in operating activities:		
Interest expense -- debt discount	10,315	10,111
Legal expense -- debt discount	1,809	-
Accretion of original issue discount on notes receivable -- related party	(3,333)	-
Stock-based compensation for license fees	218,417	56,962
Stock-based compensation to employees, directors and consultants	-	57,447
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(1,415,368)	(49,679)
Deferred offering costs	75,000	-
Accounts payable	(6,877)	78,363
Net cash used in operating activities	(2,051,700)	(1,416,694)
Cash flows from investing activities:		
Loans to related party	(840,000)	-
Proceeds from loans to related party	440,000	-
Net cash used in investing activities	(400,000)	-
Cash flows from financing activities:		
Proceeds from issuance of common stock	3,615,236	866,620
Advances from party payable	(259,411)	262,929
Deferred offering costs	-	(30,000)
Proceeds from issuance of preferred stock	-	5,880
Proceeds from notes payable	-	140,000
Proceeds from notes payable, related party	138,500	250,100
Payments on notes payable	(75,000)	-
Payments on notes payable, related party	(427,600)	(75,000)
Net cash provided by financing activities	2,991,725	1,420,529
Net increase in cash	540,025	3,835
Cash at beginning of period	4,976	1,141
Cash at end of period	\$ 545,001	\$ 4,976
Supplemental disclosures of cash flow information:		
Cash paid during the period for interest	\$ 30,569	\$ 5,000
Non-cash financing activities:		
Subscription receivable for common stock	\$ -	\$ 1,700
Fair value of warrants issued in connection with promissory note	\$ 2,235	\$ -
Deferred offering costs included in accounts payable	\$ -	\$ 45,000
Issuance of notes payable in payment of accrued expenses	\$ 29,000	\$ -
Issuance of common stock upon conversion of convertible preferred stock	\$ 1,220	\$ -

The accompanying notes are an integral part of these financial statements.

**ALZAMEND NEURO, INC.**  
**Statements of Changes in Stockholders' Equity (Deficit)**  
**Years Ended April 30, 2018 and April 30, 2017**

	<b>Series A Convertible Preferred Stock</b>		<b>Common Stock</b>		<b>Additional Paid-In Capital</b>	<b>Receivable due from Preferred Shareholder</b>	<b>Accumulated Deficit</b>	<b>Total</b>
	<b>Shares</b>	<b>Amount</b>	<b>Shares</b>	<b>Amount</b>				
BALANCES, April 30, 2016	1,000,000	\$ 100	11,600,000	\$ 1,160	\$ 13,210	\$ (3,000)	\$ (11,576)	\$ (106)
Issuance of common stock	-	-	17,550,000	1,755	863,030	-	-	864,785
Issuance of common stock for services	-	-	337,500	34	57,413	-	-	57,447
Issuance of common stock for license fees	-	-	3,386,842	338	56,624	-	-	56,962
Issuance of preferred stock	360,000	36	-	-	2,844	3,000	-	5,880
Net loss	-	-	-	-	-	-	(1,569,898)	(1,569,898)
BALANCES, April 30, 2017	1,360,000	136	32,874,342	3,287	993,121	-	(1,581,474)	(584,930)
Issuance of common stock	-	-	4,203,887	421	3,614,815	-	-	3,615,236
Issuance of common stock for conversion of Series A preferred stock	(610,000)	(61)	12,200,000	1,220	(1,159)	-	-	-
Issuance of common stock for license fees	-	-	214,967	21	218,396	-	-	218,417
Fair value of warrants issued in connection with promissory note	-	-	-	-	2,235	-	-	2,235
Net loss	-	-	-	-	-	-	(931,663)	(931,663)
BALANCES, April 30, 2018	<u>750,000</u>	<u>\$ 75</u>	<u>49,493,196</u>	<u>\$ 4,949</u>	<u>\$ 4,827,408</u>	<u>\$ —</u>	<u>\$ (2,513,137)</u>	<u>\$ 2,319,295</u>

The accompanying notes are an integral part of these financial statements.

**ALZAMEND NEURO, INC.**  
**NOTES TO FINANCIAL STATEMENTS**

**1. DESCRIPTION OF BUSINESS**

Alzamend Neuro, Inc. (the “*Company*” or “*Alzamend*”), is a specialty pharmaceutical company that was formed on February 26, 2016 to develop and commercialize patented intellectual property to prevent, treat and cure Alzheimer’s. The first patented solution that Alzamend has licensed to move to commercialization is an immunotherapy vaccine peptide that works both as a treatment and vaccine against Alzheimer’s (the “*Technology*”).

On May 29, 2018, the Company implemented a 1-for-4 Reverse Stock Split of its Common Stock. The Reverse Stock Split became effective on December 13, 2018. As a result of the Reverse Stock Split, every four (4) shares of the Company’s pre-Reverse Stock Split Common Stock were combined and reclassified into one share of the Company’s Common Stock. The number of shares of Common Stock subject to outstanding options and warrants were also reduced by a factor of four as of December 13, 2018. All historical share and per-share amounts reflected throughout the consolidated financial statements and other financial information in this filing have been adjusted to reflect the Reverse Stock Split. The par value per share of the Company’s Common Stock was not affected by the Reverse Stock Split.

The Company is devoting substantially all of its efforts towards research and development of its Technology and raising capital. The Company has not generated any product revenue to date. The Company has financed its operations to date primarily through debt financings and through the sale of its Common Stock. The Company expects to continue to incur net losses in the foreseeable future.

**2. LIQUIDITY, GOING CONCERN AND MANAGEMENT’S PLANS**

The accompanying consolidated financial statements have been prepared on the basis that the Company will continue as a going concern. As of April 30, 2018, the Company had cash of \$545,001 and an accumulated deficit of \$2,513,137. The Company has incurred recurring losses for the year ended April 30, 2018 totaling \$931,663. In the past, the Company has financed its operations principally through issuances of promissory notes and equity securities. During the year ended April 30, 2018, the Company continued to successfully obtain additional equity and debt financing.

The Company expects to continue to incur losses for the foreseeable future and needs to raise additional capital until it is able to generate revenues from operations sufficient to fund its development and commercial operations. Based on our current business plan, we believe that our cash and cash equivalents at April 30, 2018, are not sufficient to meet our anticipated cash requirements during the twelve-month period subsequent to the issuance of the financial statements included in this Annual Report on Form 1-K. Management believes that the Company has access to capital resources through potential public or private issuance of debt or equity securities. However, the Company cannot be certain that additional funding will be available on acceptable terms, or at all, in which case it may have to significantly delay, scale back or discontinue the development and/or commercialization of its product. The Company may also be required to (a) seek collaborators for its product at an earlier stage than otherwise would be desirable and on terms that are less favorable than might otherwise be available; or (b) relinquish or otherwise dispose of rights to technology or its product that the Company would otherwise seek to deploy or commercialize. These matters raise substantial doubt about the Company’s ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might become necessary should the Company be unable to continue as a going concern.

**3. SIGNIFICANT ACCOUNTING POLICIES**

**Basis of Presentation**

The financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (“*U.S. GAAP*”) and pursuant to the rules and regulations of the Securities and Exchange Commission.

## **Accounting Estimates**

The preparation of financial statements, in conformity with U.S. GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. The Company's critical accounting policies that involve significant judgment and estimates include share-based compensation and valuation of deferred income taxes. Actual results could differ from those estimates.

## **Cash and Cash Equivalents**

The Company considers all highly liquid investments with a remaining maturity of three months or less when purchased to be cash equivalents. The recorded carrying amounts of the Company's cash and cash equivalents approximate their fair value. As of April 30, 2018 and 2017, the Company had no cash equivalents.

## **Fair Value of Financial Instruments**

The Company's financial instruments are accounts payable, notes payable and notes payable, related party. The recorded values of accounts payable approximate their fair values based on their short-term nature. The recorded values of notes payable and notes payable, related party are recorded at their carrying value, net of any unamortized debt discount, which approximates their fair value based on their short-term nature.

U.S. GAAP defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The fair value hierarchy is based on three levels of inputs that may be used to measure fair value, of which the first two are considered observable and the last is considered unobservable:

Level 1: Quoted prices in active markets for identical assets or liabilities.

Level 2: Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3 assumptions: Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities including liabilities resulting from imbedded derivatives associated with certain warrants to purchase Common Stock.

## **Income Taxes**

The Company determines its income taxes under the asset and liability method. Under the asset and liability approach, deferred income tax assets and liabilities are calculated and recorded based upon the future tax consequences of temporary differences by applying enacted statutory tax rates applicable to future periods for differences between the financial statements carrying amounts and the tax basis of existing assets and liabilities. Generally, deferred income taxes are classified as current or non-current in accordance with the classification of the related asset or liability. Those not related to an asset or a liability are classified as current or non-current depending on the periods in which the temporary differences are expected to reverse. Valuation allowances are provided for significant deferred income tax assets when it is more likely than not that some or all of the deferred tax assets will not be realized.

The Company recognizes tax liabilities by prescribing a minimum probability threshold that a tax position must meet before a financial statement benefit is recognized and also provides guidance on de-recognition, measurement, classification, interest and penalties, accounting in interim periods, disclosure and transition. The minimum threshold is defined as a tax position that is more likely than not to be sustained upon examination by the applicable taxing authority, including resolution of any related appeals or litigation processes, based on the technical merits of the position. The tax benefit to be recognized is measured as the largest amount of benefit that is greater than fifty percent likely of being realized upon ultimate settlement. To the extent that the final tax outcome of these matters is different than the amount recorded, such differences impact income tax expense in the period in which such determination is made. Interest and penalties, if any, related to accrued liabilities for potential tax assessments are included in income tax expense. U.S. GAAP also requires management to evaluate tax positions taken by the Company and recognize a liability if the Company has taken uncertain tax positions that more likely than not would not be sustained upon examination by applicable taxing authorities. Management of the Company has evaluated tax positions taken by the Company and has concluded that as of April 30, 2018, there are no uncertain tax positions taken, or expected to be taken, that would require recognition of a liability that would require disclosure in the financial statements.

### **Stock-Based Compensation**

The Company accounts for stock option awards in accordance with Financial Accounting Standards Board Accounting Standards Codification (***FASB ASC***) Topic No. 718, *Compensation-Stock Compensation*. Under FASB ASC Topic No. 718, compensation expense related to stock-based payments is recorded over the requisite service period based on the grant date fair value of the awards. Compensation previously recorded for unvested stock options that are forfeited is reversed upon forfeiture. The Company uses the Black-Scholes option pricing model for determining the estimated fair value for stock-based awards. The Black-Scholes model requires the use of assumptions which determine the fair value of stock-based awards, including the option's expected term and the price volatility of the underlying stock.

The Company's accounting policy for equity instruments issued to consultants and vendors in exchange for goods and services follows the provisions of FASB ASC Topic No. 505-50, *Equity Based Payments to Non-Employees*. Accordingly, the measurement date for the fair value of the equity instruments issued is determined at the earlier of (i) the date at which a commitment for performance by the consultant or vendor is reached or (ii) the date at which the consultant or vendor's performance is complete. In the case of equity instruments issued to consultants, the fair value of the equity instrument is recognized over the term of the consulting agreement.

### **Research and Development Expenses**

Research and development costs are expensed as incurred. Research and development costs consist of scientific consulting fees and lab supplies, as well as fees paid to other entities that conduct certain research and development activities on behalf of the Company.

The Company has acquired and may continue to acquire the rights to develop and commercialize new product candidates from third parties. The upfront payments to acquire license, product or rights, as well as any future milestone payments, are immediately recognized as research and development expense provided that there is no alternative future use of the rights in other research and development projects.

### **Loss per Common Share**

The Company utilizes FASB ASC Topic No. 260, *Earnings per Share*. Basic loss per share is computed by dividing loss available to common shareholders by the weighted-average number of common shares outstanding. Diluted loss per share is computed similar to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. Diluted loss per common share reflects the potential dilution that could occur if convertible preferred stock, options and warrants were to be exercised or converted or otherwise resulted in the issuance of Common Stock that then shared in the earnings of the entity.

Since the effects of outstanding options, warrants and convertible preferred stock are anti-dilutive in the period presented, shares of Common Stock underlying these instruments have been excluded from the computation of loss per common share.

The following sets forth the number of shares of Common Stock underlying outstanding convertible preferred stock, options and warrants:

	For the Year Ended April 30,	
	2018	2017
Series A convertible preferred stock	15,000,000	27,200,000
Stock options	7,500,000	7,625,000
Warrants	43,000	37,500
	<u>22,543,000</u>	<u>34,862,500</u>

#### Reclassifications

Certain prior period amounts have been reclassified for comparative purposes to conform to the current period financial statement presentation. These reclassifications had no effect on previously reported results of operations.

#### Recent Accounting Standards

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, (“FASB”), or other standard setting bodies and adopted by the Company as of the specified effective date. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company’s financial position or results of operations upon adoption.

In August 2016, the FASB issued ASU 2016-15, *Statement of Cash Flows (Topic 230) (“ASU 2016-15”)*, which seeks to reduce the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. For public entities, ASU 2016-15 becomes effective for fiscal years beginning after December 15, 2017, including interim periods within those fiscal years, with early adoption permitted. The Company is currently evaluating the provisions of ASU 2016-15 and assessing the impact, if any, it may have on its financial position, results of operations, cash flows or financial statement disclosures.

In March 2016, the FASB issued ASU 2016-09, *Compensation - Stock Compensation (Topic 718) (“ASU 2016-09”)*, which seeks to simplify accounting for share-based payment transactions including income tax consequences, classification of awards as either equity or liabilities, and the classification on the statement of cash flows. For public entities, ASU 2016-09 becomes effective for fiscal years beginning after December 15, 2016, including interim periods within those fiscal years, with early adoption permitted. The adoption of ASU 2016-09 for the year ended April 30, 2018 did not have a material impact on the Company’s financial position or results of operations.

In January 2016, the FASB issued ASU 2016-01, *Recognition and Measurement of Financial Assets and Liabilities (“ASU 2016-01”)*. ASU 2016-01 requires equity investments (excluding equity method investments and investments that are consolidated) to be measured at fair value with changes in fair value recognized in net income. Equity investments that do not have a readily determinable fair value may be measured at cost, adjusted for impairment and observable price changes. The ASU also simplifies the impairment assessment of equity investments, eliminates the disclosure of the assumptions used to estimate the fair value that is required to be disclosed for financial instruments measured at cost on the balance sheet and requires the exit price to be used when measuring fair value of financial instruments for disclosure purposes. Under ASU 2016-01, changes in fair value (resulting from instrument-specific credit risk) will be presented separately in other comprehensive income for liabilities measured using the fair value option and financial assets and liabilities will be presented separately by measurement category and type either on the balance sheet or in the financial statement disclosures. ASU 2016-01 is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. The Company has not yet determined the effect that ASU 2016-01 will have on its financial position, results of operations, or financial statement disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements-Going Concern (Subtopic 205-40): Disclosure of Uncertainties about an Entity’s Ability to Continue as a Going Concern (“ASU 2014-15”)*. The amendments in ASU 2014-15 are intended to provide guidance on the responsibility of reporting entity management. Specifically, this ASU 2014-15 provides guidance to management related to evaluating whether there is substantial doubt about the reporting entity’s ability to continue as a going concern and about related financial statement note disclosures. Although the presumption that a reporting entity will continue to operate as a going concern is fundamental to the preparation of financial statements, prior to the issuance of ASU 2014-15, there was no guidance in (U.S. GAAP related to the concept. Due to the lack of guidance in U.S. GAAP, practitioners and their clients often faced challenges in determining whether, when, and how a reporting entity should disclose the relevant information in its financial statements. As a result, the FASB issued this guidance to require management evaluation and potential financial statement disclosures. ASU 2014-15 is effective for financial statements with periods ending after December 15, 2016. The Company adopted ASU 2014-15 during the current fiscal year and determined the effect that ASU 2014-15 did not have a material effect on its financial position, results of operations, or financial statement disclosures.



In February 2016, the FASB issued No. 2016-02, *Leases* (“**Topic 842**” or “**ASU 2016-02**”), which supersedes the guidance in former ASC 840, *Leases*. The FASB issued further updates to this guidance in July 2018 through ASU 2018-10, *Codification Improvements to Topic 842, Leases* and ASU 2018-11, *Leases* (Topic 842): *Targeted Improvements*. The new standard requires lessees to apply a dual approach, classifying leases as either finance or operating leases based on the principle of whether or not the lease is effectively a financed purchase by the lessee. This classification will determine whether lease expense is recognized based on an effective interest method or on a straight-line basis over the term of the lease. A lessee is also required to record a right-of-use asset and a lease liability for all leases with a term of greater than 12 months regardless of their classification. Leases with a term of 12 months or less will be accounted for similar to existing guidance for operating leases today. The standard is effective for interim and annual periods beginning after December 15, 2018, with early adoption permitted, and is required to be adopted using a modified retrospective approach. The Company plans to adopt this standard on May 1, 2019. ASU 2016-02 is expected to impact the Company’s consolidated financial statements as the Company has certain operating lease arrangements for which the Company is the lessee. Management is continuing to evaluate the impact the adoption of ASU 2016-02 will have on the Company’s financial position, results of operations and related disclosures. Management expects that the adoption of this standard will result in the recognition of an asset for the right to use a leased facility on the Company’s balance sheet, as well as the recognition of a liability for the lease payments remaining on the lease. While the balance sheet presentation is expected to change, management still does not expect a material change to the condensed consolidated statements of operations and comprehensive loss or cash flows.

In May 2014, the FASB issued ASU No. 2014-09, *Revenue from Contracts with Customers* (“**ASU 2014-09**”), which amends the existing accounting standards for revenue recognition. The FASB issued further updates to this guidance through ASU 2016-12 *Narrow-Scope Improvements and Practical Expedients*, ASU 2016-10 *Identifying Performance Obligations and Licensing* and ASU 2016-08 *Principal Versus Agent Considerations (Reporting Revenue Gross Versus Net)*. The new standard is based on principles that govern the recognition of revenue at an amount to which an entity expects to be entitled when products are transferred to customers. This standard was adopted on January 1, 2018 using a full retrospective application. There was no impact to the consolidated financial statements upon adoption of ASU 2014-09 as the Company had not recognized any revenue through April 30, 2018.

The Company has considered all other recently issued accounting standards and does not believe the adoption of such standards will have a material impact on its financial statements.

#### **4. NOTE RECEIVABLE, RELATED PARTY, NET**

On April 10, 2018, the Company and Avalanche International Corp., a related party (“**Avalanche**”), entered into a promissory note (the “AVLP Note”) pursuant to which the Company agreed to provide Avalanche a loan of up to \$995,500 for a period ending on April 30, 2019, subject to the terms and conditions stated in the AVLP Note. The AVLP Note accrues interest at 10% per annum and includes a 10% original issue discount. At April 30, 2018, the Company has provided loans to Avalanche in the principal amount of \$800,000, of which \$400,000 was repaid, resulting in net loans to Avalanche of \$400,000 and an original issue discount of \$40,000.

In accordance with ASC No. 310, *Receivables* (“**ASC 310**”), the Company accounts for its AVLP Note at amortized cost, which represents the amount at which the promissory note was acquired, adjusted for accrued interest and accretion of original issue discount. Interest is accreted using the effective interest method. The Company records interest on an accrual basis and recognizes it as earned in accordance with the contractual terms of the promissory note. The original issue discount of \$40,000 is being amortized as interest income through the maturity date. During the year ended April 30, 2018, the Company recorded \$3,333 of interest income for the discount accretion and recorded contractual interest income from the stated interest rate of \$4,008.

## 5. PREPAID EXPENSES AND OTHER CURRENT ASSETS

Prepaid expenses and other current assets are as follows:

	April 30, 2018	April 30, 2017
Prepaid expenses	\$ 1,446,667	\$ 50,617
Interest receivable	4,008	-
Other receivables	17,010	1,700
Total prepaid expenses and other current assets	<u>\$ 1,467,685</u>	<u>\$ 52,317</u>

### *Alzamend Consulting Agreement*

The Company entered into a five year consulting agreement with Spartan pursuant to which Spartan has agreed to provide consulting services with respect to general corporate matters, including, but not limited to, advice and input with respect to raising capital, potential merger and acquisition transactions, identifying suitable personnel for management, developing corporate structure and finance strategies, assisting the Company with strategic introductions, assisting management with enhancing corporate and shareholder value and introducing the Company to potential investors. In December 2017, since the maximum amount was raised in the Offering, the Company paid to Spartan a consulting fee of \$1,400,000 for the services to be rendered over the sixty (60) month term of this consulting agreement.

## 6. INCOME TAXES

The Company has fully reserved the net deferred income tax assets by taking a full valuation allowance against these assets. As a result of this decision, during the years ended April 30, 2018 and 2017, the Company did not recognize any income tax benefit as a result of its net loss. The table below shows the balances for the deferred income tax assets and liabilities as of the date indicated.

	April 30, 2018	April 30, 2017
Deferred income tax asset:		
Net operating loss carryover	\$ 517,972	\$ 444,110
Other temporary differences	7,637	91,033
Total deferred tax asset	(25,609)	535,143
Valuation allowance	25,609	(535,143)
Deferred income tax asset, net of allowance	<u>\$ -</u>	<u>\$ -</u>

The income tax provision (benefit) consists of the following:

	For the Year Ended April 30, 2018	2017
Federal and State		
Current	\$ -	\$ -
Deferred	9,543	(535,143)
Valuation allowance	(9,543)	535,143
Income tax provision (benefit)	<u>\$ -</u>	<u>\$ -</u>

On December 22, 2017, the U.S. enacted the Tax Cuts and Jobs Act (“tax reform” or “Tax Act”), which among other things, lowered the U.S. statutory tax rate from 35% to 21% effective January 1, 2018. Consequently, the Company applied a blended U.S. statutory federal income tax rate of 29.7% for fiscal 2018. During the years ended April 30, 2018 and 2017, the Company did not recognize income tax expense. The Company’s effective tax rate was 0% for the years ended April 30, 2018 and 2017. The effective tax rate differed primarily due to the change in the valuation allowance, primarily related to the revaluation of deferred tax assets and liabilities to reflect the new federal tax rate. The reconciliation of income tax attributable to operations computed at the U.S. Federal statutory income tax rate of 29.7% to income tax expense is as follows:

	<b>For the Year Ended April 30,</b>	
	<b>2018</b>	<b>2017</b>
Tax benefit at U.S. Federal statutory tax rate	(29.7%)	(34.0%)
Increase (decrease) in tax rate resulting from:		
Allowance against deferred tax assets	(1.0%)	34.0%
Nondeductible meals & entertainment expense and other	0.1%	0.1%
Taxes in respect of prior years	0.0%	(0.1%)
Changes in federal tax rate	30.6%	0.0%
Effective tax rate	0.0%	0.0%

At April 30, 2018, the Company had total domestic Federal net operating loss carryovers of approximately \$2,467,000 available to offset future taxable income. Federal net operating loss carryovers (“**NOLs**”) expire beginning in 2026. The Company has not filed its 2016 through 2018 Federal income tax returns. The Company will not be able to utilize these carryovers until the related tax returns are filed. In accordance with Section 382 of the Internal Revenue Code, deductibility of the Company’s NOLs may be subject to an annual limitation in the event of a change of control as defined under the regulations.

In assessing the realization of deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which temporary differences representing net future deductible amounts become deductible. Management considers the scheduled reversal of deferred tax assets, projected future taxable income and tax planning strategies in making this assessment. After consideration of all of the information available and due to the substantial doubt related to the Company’s ability to continue as a going concern and utilize its deferred tax assets, the Company recorded a full valuation allowance of the deferred tax asset. For the year ended April 30, 2018 the valuation allowance has decreased by \$9,534.

The 2016 through 2018 tax years remains open to examination by the Internal Revenue Service. The IRS has the authority to examine such tax year until the applicable statute of limitations expire.

## 7. STOCK-BASED COMPENSATION

On April 30, 2016, the Company’s shareholders approved the Company’s 2016 Stock Incentive Plan (the “Plan”). The Plan provides for the issuance of a maximum of fifty million (12,500,000) shares of the Company’s Common Stock to be offered to the Company’s directors, officers, employees, and consultants. Options granted under the Plan have an exercise price equal to or greater than the fair value of the underlying Common Stock at the date of grant and become exercisable based on a vesting schedule determined at the date of grant. The options expire between 5 and 10 years from the date of grant. Restricted stock awards granted under the Plan are subject to a vesting period determined at the date of grant.

During the years ended April 30, 2018 and 2017, the Company did not grant any equity-based awards from the Plan and did not recognize any stock-based compensation expense from previous grants made pursuant to the Plan. During the year ended April 30, 2017, the Company did issue 337,500 shares of Common Stock to consultants outside of the Plan and recognized \$57,447 in stock-based compensation expense the fair value of which was determined from recent sales of the Company’s Common Stock to third parties. Further, pursuant to the terms of the License Agreement, during the years ended April 30, 2018 and 2017, the Company issued 214,967 and 3,386,842 shares of its Common Stock and recognized \$218,417 and \$56,962, respectively, in license fees.

All options that the Company grants are granted at the per share fair value on the grant date. Vesting of options differs based on the terms of each option. The Company has valued the options at their date of grant utilizing the Black Scholes option pricing model. As of the issuance of these financial statements, there was not an active public market for the Company's shares. Accordingly, the fair value of the underlying options was determined based on the historical volatility data of similar companies, considering the industry, products and market capitalization of such other entities. The risk-free interest rate used in the calculations is based on the implied yield available on U.S. Treasury issues with an equivalent term approximating the expected life of the options as calculated using the simplified method. The expected life of the options used was based on the contractual life of the option granted. Stock-based compensation is a non-cash expense because the Company settles these obligations by issuing shares of the Company's Common Stock from its authorized shares instead of settling such obligations with cash payments.

A summary of option activity under the Company's Plan as of April 30, 2018 and 2017, and changes during the years ended are as follows:

	Shares Available for Grant	Number of Shares	Outstanding Options		
			Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (years)	Aggregate Intrinsic Value
April 30, 2016	4,875,000	7,625,000	\$ 0.0004	10.00	\$ -
April 30, 2017	4,875,000	7,625,000	\$ 0.0004	9.00	\$ 1,294,804
Forfeited	125,000	(125,000)	\$ 0.0004		
April 30, 2018	5,000,000	7,500,000	\$ 0.0004	8.00	\$ 7,497,000

The aggregate intrinsic value in the table above represents the total pretax intrinsic value (i.e., the difference between the fair value price on the respective date and the exercise price, times the number of shares) that would have been received by the option holders had all option holders exercised their options. There have not been any options exercised during the year ended April 30, 2018.

As of April 30, 2018, there were no unvested stock options and accordingly no unrecognized compensation cost related to unvested stock options.

## 8. WARRANTS

On October 1, 2017, the Company issued warrants to purchase an aggregate of 5,500 shares of Common Stock at an exercise price equal to \$1.20 per share of Common Stock in connection with the issuance of a promissory note in the aggregate principal amount of \$44,000 to DPW Holdings, Inc., a related party (See Note 11).

The following table summarizes information about Common Stock warrants outstanding at April 30, 2018:

Outstanding				Exercisable	
Exercise Price	Number Outstanding	Weighted Average Remaining Contractual Life (years)	Weighted Average Exercise Price	Number Exercisable	Weighted Average Exercise Price
\$0.004	37,500	0.96	\$0.004	37,500	\$0.004
\$1.20	5,500	2.42	\$1.20	5,500	\$1.20
\$0.004 - \$1.20	43,000	1.14	\$0.156	43,000	\$0.156

## 9. RELATED PARTY TRANSACTIONS

As of April 30, 2016, the Company had sold 1,000,000 shares of Series A Convertible Preferred Stock to MCKEA Holdings, LLC (“**MCKEA**”), a related party (See Note 12).

On May 1, 2016, the Company entered into a Management Services Agreement (“**Management Agreement**”) with Avalanche International Corp. (“**Avalanche**”), a related party. The Company’s officers and directors are also officers and directors of Avalanche. Further, MCKEA is the majority member of Philou Ventures, LLC, which is the controlling shareholder of Avalanche. Pursuant to the terms of the Management Services Agreement, Avalanche shall provide management, consulting and financial services to Alzamend. Such services shall include advice and assistance concerning any and all aspects of operations, planning and financing of Alzamend and conducting relations with accountants, attorney, financial advisors and other professionals. The term of the Management Services Agreement, as amended, is for the period May 1, 2016 to December 31, 2017 and may be extended by written agreement. The Company initially paid \$40,000 per month for these services and, beginning February 2017, is currently paying \$20,000 per month. During the years ended April 30, 2018 and 2017, the Company recognized \$240,000 and \$420,000, respectively, in management fees. At April 30, 2018 and April 30, 2017, \$0 and \$180,000, respectively, were included within related party payable on the Company’s balance sheet. The MSA was terminated on December 31, 2018.

On June 28, 2017, MCKEA and Spartan Capital Securities, LLC (“**Spartan**”) entered into a five-year consulting agreement (the “MCKEA Consulting Agreement”). Pursuant to the MCKEA Consulting Agreement, upon the receipt by the Company of no less than \$2,500,000 in gross proceeds from the PPM, MCKEA will transfer to Spartan 5,000,000 shares of Alzamend Common Stock. During the term of the MCKEA Consulting Agreement, Spartan will provide consulting services related to general corporate and other matters related to MCKEA’s investment in the Company such as advice on mergers and acquisition transactions, finance strategies, identification of potential management candidates and other strategic introductions.

The amount due at April 30, 2018 and 2017 to MCKEA and the Company’s officers for reimbursement of expenses paid and incurred by these related parties was \$6,636 and \$58,373, respectively. The amounts are included within related party payable on the Company’s balance sheet.

The amount were no amounts due at April 30, 2018 for notes payable to related parties. The amount due at April 30, 2017 to related parties from short-term loans, inclusive of unamortized original discount of \$6,271, was \$253,829. The amounts are included within notes payable, related parties, on the Company’s balance sheet (See Note 11).

On April 10, 2018, the Company and Avalanche International Corp., a related party (“**Avalanche**”), entered into a promissory note (the “AVLP Note”) pursuant to which the Company agreed to provide Avalanche a loan of up to \$995,500 for a period ending on April 30, 2019, subject to the terms and conditions stated in the AVLP Note. The AVLP Note accrues interest at 10% per annum and includes a 10% original issue discount. At April 30, 2018, the Company has provided loans to Avalanche in the principal amount of \$800,000, of which \$400,000 was repaid, resulting in net loans to Avalanche of \$400,000 and an original issue discount of \$40,000.

In accordance with ASC No. 310, Receivables (“**ASC 310**”), the Company accounts for its AVLP Note at amortized cost, which represents the amount at which the promissory note was acquired, adjusted for accrued interest and accretion of original issue discount. Interest is accreted using the effective interest method. The Company records interest on an accrual basis and recognizes it as earned in accordance with the contractual terms of the promissory note. The original issue discount of \$40,000 is being amortized as interest income through the maturity date. During the year ended April 30, 2018, the Company recorded \$3,333 of interest income for the discount accretion and recorded contractual interest income from the stated interest rate of \$4,008 (See Note 4).

## 10. NOTES PAYABLE

During January 2017, the Company entered into a promissory note and received net proceeds of \$65,000. As consideration for this loan, the Company issued a promissory note in the aggregate principal amount of \$75,000, which included an OID and fees of \$10,000. The OID was amortized as non-cash interest expense over the term of the debt. During the years ended April 30, 2018 and 2017, interest expense of \$3,618 and \$6,382, respectively was recorded from the debt discount amortization. The promissory note accrued interest at 15% per year and during the years ended April 30, 2018 and 2017, the Company recorded \$16,838 and \$2,774, respectively, in interest. This loan was repaid during the year ended April 30, 2018. At April 30, 2017, the outstanding balance on the promissory note, inclusive of unamortized OID of \$3,618, was \$71,382.

## 11. NOTES PAYABLE, RELATED PARTY

At April 30, 2017, the outstanding balance on short term borrowings from Avalanche, a related party, was \$180,100. During the year ended April 30, 2018, Avalanche provided an additional \$123,500 in short term financing. This short-term obligation was non-interest bearing, due upon demand and repaid during the year ended April 30, 2018.

During January 2017, the Company entered a promissory note and received net proceeds of \$70,000 from Gary Gottlieb, a related party. As consideration for this loan, the Company issued a promissory note in the aggregate principal amount of \$80,000, which included an OID of \$10,000. The OID was amortized as non-cash interest expense over the term of the debt. During the years ended April 30, 2018 and 2017, interest expense of \$6,271 and \$3,729 was recorded from the debt discount amortization. This promissory note accrued interest at 15% per year and during the years ended April 30, 2018 and 2017, the Company recorded \$6,272 and \$3,614, respectively, in interest. The Company repaid this loan during the year ended April 30, 2018.

On October 1, 2017, the Company entered into a promissory note in the principal amount of \$47,520 with DPW Holdings, Inc., a related party (**DPW**). The promissory note included an OID of \$3,520 resulting in net proceeds to the Company of \$44,000, yielded 8% simple interest on the principal amount, and was due on August 16, 2018. As additional consideration, the Company also issued to DPW a warrant to purchase 5,500 shares of Common Stock at an exercise price of \$1.20 per share. The Company recorded debt discount of \$2,235 based on the estimated fair value of the 5,500 warrants. Prior to April 30, 2018, the Company repaid the outstanding balance to DPW.

## 12. EQUITY TRANSACTIONS

### *Series A Preferred Stock*

The Board of Directors has designated 1,360,000 shares of its Preferred Stock as “Series A Convertible Preferred Stock” (the **Series A Preferred Shares**). The Series A Preferred Shares convey no dividend rights except as may be declared by the Board in its sole and absolute discretion, out of funds legally available for that purpose. Holders of Series A Preferred Shares are entitled to 50 non-cumulative votes per share on all matters presented to our stockholders for action. In addition, the affirmative vote of the holders of a majority of the Series A Preferred then outstanding, voting as a separate class, is required for the Company to do any of the following:

- amend, alter or repeal any of the preferences or rights of the Series A Preferred Shares;
- authorize any reclassification of the Series A Preferred Shares;
- increase the authorized number of Series A Preferred Shares; or
- create any class or series of shares ranking prior to the Series A Preferred Shares as to dividends or liquidation.

The Series A Preferred Shares are not entitled to preemptive rights. In the event of any dissolution, liquidation or winding up of the Company, whether voluntary or involuntary, the Holders of Series A Preferred Shares shall be entitled to participate in any distribution out of the assets of the Company on an equal basis per share with the holders of the Common Stock.

Holders of Series A Preferred Shares have the right to convert their shares into shares of Common Stock at any time at a conversion rate equal to twenty (20) shares of Common Stock for every one (1) Series A Preferred Share. The conversion rate is not subject to anti-dilution adjustments.

On April 1, 2016, the Company entered into a subscription agreement with MCKEA Holdings, LLC (**MCKEA**). The Company issued and sold to MCKEA 1,000,000 shares of Series A Preferred Shares that are convertible into 20,000,000 shares of Common Stock that carry the voting power of 50,000,000 shares of Common Stock. Kristine L. Ault, the wife of Milton C. Ault III, Chairman of the Company’s Board of Directors, is the managing member of MCKEA. The issuance resulted in aggregate gross proceeds to the Company of \$8,000, of which \$5,000 was paid directly to a third party for legal services in April 2016 and \$3,000 was received during the year ended April 30, 2017.

On May 30, 2016, the Company entered into subscription agreements for the sale of 360,000 shares of Series A Preferred Stock to two investors at \$0.008/share for an aggregate purchase price of \$2,880. The Series A Preferred Stock is convertible into 7,200,000 shares of Common Stock.

#### *Common Stock*

On May 27, 2016, the Company's Board of Directors approved a Certificate of Amendment to the Company's Certificate of Incorporation increasing its authorized shares of Common Stock from 150,000,000 to 300,000,000.

During April 2016, the Company entered into subscription agreements with multiple investors. The Company issued and sold to these investors 11,600,000 shares of its Common Stock at \$0.0004 per share. The issuance resulted in aggregate gross proceeds to the Company of \$4,640, of which \$1,105 was received in April 2016 and the remainder of \$3,535 was received in May 2016.

During May 2016, the Company entered into subscription agreements with multiple investors. The Company issued and sold to these investors 11,675,000 shares of its Common Stock at \$0.0004 per share. The issuance resulted in aggregate gross proceeds to the Company of \$4,670, of which \$2,970 has been received. The Company has recorded a receivable at October 31, 2017 and April 30, 2017, for the remaining balance due of \$1,700 recorded in subscription receivable on the balance sheet.

On June 23, 2016 and July 6, 2016, the Company entered into subscription agreements with EAV, LLC for the purchase of 500 units at \$1,000 for each unit purchased. Each unit consisted of 5,875 shares of Common Stock. In aggregate, EAV purchased a total of 1,000 units, representing 5,875,000 shares of Common Stock for an aggregate of \$1,000,000, or approximately \$0.1704 per share, pursuant to the terms of a Private Placement Memorandum dated June 3, 2016. Payment for the 1,000 units was received between July 7, 2016 and August 2, 2016. In conjunction with the Private Placement Memorandum, the Company incurred \$100,000 in placement fees to Palladium Capital Advisors, LLC, and \$39,885 in legal and filing fees, resulting in net proceeds to the Company of \$860,115.

On April 5, 2016, the Company entered into a retainer agreement for legal representation in connection with a selling shareholder registration on Form 1-A (the "**Offering Circular**") for a Regulation A+ offering (the "**Reg A+ Offering**"). Pursuant to the terms of the retainer agreement the Company agreed to pay a fee of \$75,000 of which an initial payment of \$25,000 was due upon execution of the retainer agreement, \$25,000 is due prior to the filing of the initial Offering Circular and \$25,000 is due upon qualification of the Offering Circular by the Securities and Exchange Commission. The total payments of \$75,000 are reflected as deferred offering costs, of which \$45,000 has been included in accounts payable. During June 2017, the Company raised \$74,926 in the Reg A+ Offering, the total amount of the fee will be offset against the proceeds received by reducing additional paid in capital and the balance of \$74 will be recorded as legal expense.

An exclusive license agreement with sublicensing terms was made effective on May 1, 2016, as amended on August 17, 2017, (the "**Effective Date**") by and between the University, and a direct support organization of the University and the Company (the "**License Agreement**"). There are certain license fees and milestone payments required to be paid for the licensing of an immunotherapy vaccine peptide that is designed to be used both as a treatment and vaccine against Alzheimer's (the "**Technology**"), pursuant to the terms of the License Agreement with the Licensor and the University. Pursuant to the terms of the License Agreement, the Licensor is entitled to receive that number of shares of the Company's Common Stock equal to five percent (5%) of the total number of issued and outstanding shares outstanding, subject to additional issuances until such time as the Company has received a total of \$5 million in cash in exchange for the Company's equity securities. During the year ended April 30, 2017, the Company issued 3,386,842 shares of its Common Stock and recognized \$56,962 in license fees pursuant to the License Agreement. During the year ended April 30, 2018, the Company issued 53,742 shares of its Common Stock and recognized \$56,962 in license fees pursuant to the License Agreement. The amount of the license fees was based on the fair value of the Company's Common Stock on the date of issuance. Fair value was determined from recent sales of the Company's Common Stock to third parties.

There are certain initial license fees and milestone payments required to be paid by us to the Licensor pursuant to the terms of the License Agreement. The License Agreement requires the Company to pay royalty payments of four percent (4%) on net sales of products developed from the licensed technology. The Company has already paid an initial license fee of \$200,000. As an additional licensing fee, the Licensor is entitled to receive that number of shares of the Company's Common Stock equal to five percent (5%) of the total number of issued and outstanding shares outstanding on May 1, 2016, subject to additional issuances until such time as the Company has received a total of \$5 million in cash in exchange for the Company's equity securities.

During the year ended April 30, 2017, the Company issued 337,500 shares of Common Stock to service providers for total stock-based compensation of \$57,446. All of the shares of Common Stock were valued based on the fair value of the Company's Common Stock on the date of issuance. Fair value was determined from recent sales of the Company's Common Stock to third parties. These issuances included 25,000 shares of Common Stock, valued at \$4,255, to a related party.

In December 2016, the SEC qualified the Company's Regulation A Offering Statement pursuant to which the Company sought to raise \$50,000,000 from the sale of Common Stock at a price of \$8.00 per share. The Company sold 9,366 shares of Common Stock and received gross proceeds of \$74,926 in the offering, which closed on June 15, 2017.

On October 19, 2017, the Company entered into subscription agreements for the purchase of 107.7 units at \$10,000 for each unit purchased. Each unit consisted of 10,000 shares of Common Stock. In aggregate, the 107.7 units represented 1,077,000 shares of Common Stock for an aggregate purchase price of \$1,077,000, or \$1.00 per share, pursuant to the terms of a Private Placement Memorandum dated August 17, 2017 (the "**PPM**"). In conjunction with this PPM, the Company incurred \$107,700 in placement fees and \$57,900 in legal and filing fees, resulting in net proceeds to the Company of \$911,400.

Between December 13, 2017 and December 29, 2017, the Company entered into subscription agreements for the purchase of 311.75 units at \$10,000 for each unit purchased. Each unit consisted of 10,000 shares of Common Stock. In aggregate, the 311.75 units represented 3,117,500 shares of Common Stock for an aggregate purchase price of \$3,117,500, or \$1.00 per share, pursuant to the terms of a Private Placement Memorandum dated August 17, 2017 (the "**PPM**"). In conjunction with this PPM, the Company incurred \$311,750 in placement fees and \$35,623 in legal and filing fees, resulting in net proceeds to the Company of \$2,770,128.

On January 8, 2018, the Company received notices of conversion from two investors that had purchased 360,000 shares of Series A Preferred Stock. The Series A Preferred Stock was converted into 7,200,000 shares of Common Stock.

#### *Placement Agreement*

The Company has agreed with Spartan Capital Securities, LLC ("**Spartan**"), the placement agent in the Company's PPM offering (the "**Offering**"), as follows:

#### Use of Proceeds

The Company will apply the net proceeds from the Offering to include the retention of a FDA consulting firm, payment of the IND and all associated costs and the launch of a First Stage Clinical Trial with up to 20 human patients along with limited operational expenses.

#### Corporate Governance

During the period commencing on December 29, 2017 and ending at such time as the Company's Common Stock is listed on a national securities exchange, Spartan will have the right to designate one member of the Company's Board of Directors (the "**Board**"). If Spartan does not elect to designate a member of the Board, then the Company will permit a representative of Spartan to attend all meetings of the Board as an observer.

In addition, commencing within twelve (12) to twenty-four (24) months from December 29, 2017, the Board will be comprised of two inside directors and three independent directors (as such term is defined by Rule 5605 of the NASDAQ Stock Market). This covenant will expire upon the listing of the Company's Common Stock on a national securities exchange.



### Registration Rights

Subject to applicable law or regulations including but not limited to Rule 415 of the Securities Act the Company, within one hundred and eighty (180) days of the final closing of an initial public offering of the Company's equity securities, file a registration statement on Form S-1 with the Securities and Exchange Commission, which registration statement will cover the shares of Common Stock issuable to the Placement Agent pursuant to the MCKEA Consulting Agreement discussed above as well as the shares of Common Stock issued in the Offering.

### **13. SUBSEQUENT EVENTS**

In accordance with FASB ASC 855-10, the Company has analyzed its operations subsequent to April 30, 2018 and has determined that it does not have any material subsequent events to disclose in these financial statements except for the following.

On July 2, 2018, the Company obtained two royalty-bearing, exclusive worldwide licenses from the University, to a therapy known as LiProSal™ to mitigate extreme agitation and forestall other deterioration as displayed by patients with up to moderate AD. LiProSal™ is an ionic cocrystal of lithium for the treatment of Alzheimer's and possibly other neurodegenerative diseases. Recent evidence suggests that lithium may be efficacious for both the treatment and prevention of AD. Unlike traditional medications, which only address a single therapeutic target, lithium appears to be neuroprotective through several modes of action. For example, it exerts neuroprotective effects, in part, by increasing the brain-derived neurotrophic factor leading to restoration of learning and memory based on the results with some of the animal subjects during the preclinical studies. Another neuroprotective mechanism of lithium is attenuation of the production of inflammatory cytokines like IL-6 and nitric oxide in activated microglia. Alzamend is continuing to work with two of the inventors of this therapeutic, both at the USF Morsani College of Medicine; Jun Tan, PhD, MD, Professor at the College of Medicine Neurosurgery, Endowed Chair, College of Medicine Psychiatry and Behavioral Neurosciences and the Silver Endowed Chair in Developmental Neurobiology, Department of Psychiatry & Behavioral Medicine and Roland D. Shytle, PhD, Associate Professor, Center of Excellence for Aging & Brain Repair. Dr. Tan and Dr. Shytle with Adam J. Smith, PhD., MSBE, Michael Zaworotko, PhD., and Naga Duggirala, PhD., all formerly with the University of South Florida, have designed, synthesized and characterized this ionic cocrystal of lithium, which Alzamend has named LiProSal™. LiProSal™ has been shown to exhibit improved pharmacokinetics compared to current FDA-approved lithium-based drugs as well as bioactive in many in vitro models of Alzheimer's disease. LiProSal™ may prove to be a major improvement over current lithium-based treatments and may also represent a means of treating AD.

There are certain license fees and milestone payments required to be paid for the licensing of the LiProSal™ technology, pursuant to the terms of the Standard Exclusive License Agreements with Sublicensing Terms, both dated June 21, 2018 (the "LiProSal™ License Agreements") with the Licensor and the University. In addition, a royalty payment of 3% is required pursuant to License #18110 while License #1811 requires a royalty payment of 1.5% on net sales of products developed from the licensed technology. For the two LiProSal™ License Agreements, in the aggregate, the Company is required to pay initial license fees of \$50,000 no later than July 31, 2018 and \$150,000 no later than October 31, 2018, although the Company is in discussions with the University to defer the payment due date of the initial license fees. As an additional licensing fee, the Licensor is entitled to receive that number of shares of the Company's Common Stock equal to three percent (3%) of the sum of the total number of issued and outstanding shares. Additionally, the Company is required to pay milestone payments on the due dates to Licensor for the license of the technology, as follows:

<b>Payment</b>	<b>Due Date</b>	<b>Event</b>
\$ 50,000	November 1, 2019	Pre-IND meeting
\$ 65,000	6 months from IND filing date	IND application filing
\$ 190,000	12 months from IND filing date	Upon first dosing of patient in a clinical trial
\$ 500,000	12 months from first patient dosing	Upon Completion of first clinical trial
\$ 1,250,000	12 months from completion of the first Phase II clinical trial	Upon first patient treated in a Phase III Clinical Trial
\$ 10,000,000	8 years from the Effective Date of the Agreement	Upon FDA Approval

On May 29, 2018, the Company implemented a 1-for-4 Reverse Stock Split of its Common Stock. The Reverse Stock Split became effective on December 13, 2018. As a result of the Reverse Stock Split, every four (4) shares of the Company's pre-Reverse Stock Split Common Stock were combined and reclassified into one share of the Company's Common Stock. The number of shares of Common Stock subject to outstanding options and warrants were also reduced by a factor of four as of December 13, 2018. All historical share and per-share amounts reflected throughout the consolidated financial statements and other financial information in this filing have been adjusted to reflect the Reverse Stock Split. The par value per share of the Company's Common Stock was not affected by the Reverse Stock Split.

## Item 8. EXHIBITS

### Index to Exhibits

Exhibit No.	Exhibit Description
2.1	Certificate of Incorporation**
2.2	Bylaws**
4.1	Form of Subscription Agreement**
6.1	Standard Exclusive License Agreement with Sublicensing Terms with the University of South Florida Research Foundation, Inc., dated May 1, 2016**
6.2	Management Services Agreement, as amended, with Avalanche International Corp., dated May 1, 2016**
6.3	Standard Exclusive License Agreement with Sublicensing Terms Number LIC18110 with the University of South Florida Research Foundation, Inc., dated July 2, 2018*
6.4	Standard Exclusive License Agreement with Sublicensing Terms Number LIC18111 with the University of South Florida Research Foundation, Inc., dated July 2, 2018*
8.1	Escrow Agreement, dated May 24, 2016**

\* Filed herewith

\*\* Previously filed

## SIGNATURES

Pursuant to the requirements of Regulation A, the issuer has duly caused this annual report on Form 1-K to be signed on its behalf by the undersigned, thereunto duly authorized.

**Alzamend Neuro, Inc.**

Date: February 21, 2019

By: /s/ Stephan Jackman

Stephan Jackman  
Chief Executive Officer  
(Principal Executive Officer).

Pursuant to the requirements of Regulation A, this annual report on Form 1-K has been signed below by the following persons on behalf of the issuer and in the capacities and on the dates indicated.

Date: February 21, 2019

By: /s/ Kenneth S. Cragun

Kenneth S. Cragun  
Chief Financial Officer  
(Principal Financial Officer,  
Principal Accounting Officer).

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**STANDARD EXCLUSIVE LICENSE AGREEMENT**  
**WITH SUBLICENSING TERMS**

Agreement # Number LIC18110.

This Agreement is made effective July 02, 2018, (the "Effective Date") by and between the University of South Florida Research Foundation, Inc. (hereinafter called "Licensor"), a nonstock, nonprofit Florida corporation, under Chapter 617 Florida Statutes, and a direct support organization of the University of South Florida ("University") pursuant to section 1004.28 Florida Statutes and Alzamend Neuro Inc. (hereinafter called "Licensee"), a small corporation organized and existing under the laws of Delaware;

WHEREAS, Licensor is the exclusive licensee of certain inventions that are described in the "Licensed Patents" defined below (Licensor Reference #12B100), and Licensor is willing to grant a license to Licensee under any one or all of the Licensed Patents and Licensee desires a license under all of them;

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, the parties covenant and agree as follows:

**Section 1      Definitions**

- 1.1 "Affiliate" means: (a) any person or entity which controls at least fifty percent (50%) of the equity or voting stock of the Licensee or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by the Licensee or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50%) of Licensee or (d) any entity in which any officer or employee is also an officer or employee of Licensee or any person who is an officer or employee of Licensee or (e) any other relationship as in fact, constitutes actual control.
- 1.2 "Development Plan" means the written report summarizing the development activities that are to be undertaken by the Licensee to bring Licensed Products and/or Licensed Processes to the market. The Development Plan is attached as Appendix A.
- 1.3 "Development Report" means a written account of Licensee's progress under the Development Plan having at least the information specified on Appendix B to this Agreement, and shall be sent to the address specified on Appendix B .
- 1.4 "Investigator" means Drs. Roland (Doug) Shytle, Michael Zaworotko, Adam Smith and Naga Duggirala, while employed by Licensor.
- 1.5 "Know-How" means unpatented technology and/or information that was developed by the Investigator, including without limitation methods, processes, techniques, compounds, cell lines, materials, sequences, drawings, indications, data, results of tests, or studies, plans, and expertise, whether patentable or not, which relates specifically to the Licensed Patents and existing on the date hereof, only to the extent wholly owned and controlled by Licensor, except that, Know-How shall not include the Licensed Patents.
- 1.6 "Licensed Field" shall be limited to the use of LiSPro for the treatment of Alzheimer's Disease.

- 1.7 “Licensed Patents” means all of the following Licensor intellectual property:
- 1.7.1 the patent(s)/patent application(s) identified on Schedule 1 hereto;
  - 1.7.2 any and all United States and foreign patent applications claiming priority to any of the patent(s) and patent application(s) identified on Schedule 1 hereto (except that in the case of continuation-in-part application(s), only to the extent that the subject matter claimed in such continuation-in-part application(s) is supported under 35 U.S.C 112 in the patent(s)/patent application(s) identified on Schedule 1 hereto); and
  - 1.7.3 any and all patents issuing from the patent applications identified in section 1.6.1 and 1.6.2, including, but not limited to, letters patents, patents of addition, reissues, re-examinations, extensions, restorations, and supplementary protection certificates;
- all to the extent owned or controlled by Licensor.
- 1.8 “Licensed Product” and “Licensed Process” means:
- 1.8.1 In the case of a Licensed Product, any product or part thereof, on a country-by-country basis, that:
    - (a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which such product is made, used, imported or sold; or
    - (b) is manufactured by using a process that is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which any such process is used or in which any such product is used, imported, or sold; or
    - (c) incorporates, utilizes, or was developed utilizing, Know-How or that is manufactured using Know-How or using a process developed using Know-How.
  - 1.8.2 In the case of a Licensed Process, any process, on a country-by-country basis, that:
    - (a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents in any country in which such process is practiced; or
    - (b) incorporates, utilizes, or was developed utilizing, Know-How.
- 1.9 “Licensed Territory” shall be worldwide.
- 1.10 “Net Sales” means the total dollar amount invoiced on sales of Licensed Product and/or Licensed Processes by Licensee, Sublicensee or Affiliates. Total amount invoiced may include only promotional discounts allowed in amounts customary in the trade.
- 1.11 “Patent Challenge” means a challenge to the validity, patentability, enforceability and/or non-infringement of any of the Licensed Patents or otherwise opposing any of the Licensed Patents.
- 1.12 “Sublicense” means, directly or indirectly, to sublicense, grant any other right with respect to, or agree not to assert, any right licensed to Licensee under this Agreement.
- 1.13 “Sublicensee” means any third party to whom Licensee grants a Sublicense.

## **Section 2**      **Grant**

### 2.1      License.

#### 2.1.1      License Under Licensed Patents and Know-How

Subject to the terms of this Agreement, Licensors hereby grants to Licensee: a) a royalty-bearing, exclusive license, limited to the Licensed Field and the Licensed Territory, under the Licensed Patents to make, have made, develop, use, lease, import, export, offer to sell, sell and have sold Licensed Products and/or Licensed Processes, and b) a royalty bearing, non-exclusive license, limited to the Licensed Field and the Licensed Territory, under the Know-How to make, have made, develop, use, lease, import, export, offer to sell, sell and have sold Licensed Products and/or Licensed Processes. Licensors reserves to itself and to all nonprofit entities with which it collaborates the right under the Licensed Patents to make, have made, develop, import and use Licensed Products and Licensed Processes solely for their internal research, clinical and educational purposes. In addition, Licensors reserves to itself, as well as to all non-profit research institutions with which it collaborates, the right to use materials that might be covered under Licensed Patents solely for their internal research, educational, and clinical purposes and to meet all applicable governmental and peer review journal requirements governing the transfer of materials.

2.1.2      The license granted hereunder shall not be construed to confer any rights upon Licensee by implication, estoppel, or otherwise as to any technology not part of the Licensed Patents in the specified Licensed Field and specified Licensed Territory.

### 2.2      Sublicense.

2.2.1      Licensee may grant written Sublicenses under the Licensed Patents to third parties upon Licensors' approval, which approval shall not be unreasonably withheld. Any agreement granting a Sublicense shall state that the Sublicense is subject to the terms and conditions of this Agreement and to the termination of this Agreement. Licensee shall have the same responsibility for the activities of any Sublicensee or Affiliate as if the activities were directly those of Licensee.

2.2.2      Licensee shall provide Licensors with an unredacted copy of each Sublicense agreement and any agreement which transfers intellectual property rights granted hereunder, at least thirty (30) days prior to the execution of the Sublicense agreement.

2.2.3      In the event that Licensors notifies Licensee in writing of a third party's interest in a market or territory which Licensee is not addressing at the time of receipt of the notice, Licensee shall respond to Licensors in writing within thirty (30) days of receipt of such notice to inform Licensors whether Licensee intends to pursue the market or territory. If in such response, Licensee elects to forego the market or territory, Licensors may terminate in said market or territory the license granted in 2.1.1.

## **Section 3**      **Due Diligence**

### 3.1      Development.

3.1.1      Licensee agrees to and warrants that:

- (a) it has, or will obtain, the expertise necessary to independently evaluate the inventions of the Licensed Patents and Know-How; and
- (b) it will actively and diligently pursue the Development Plan, see Appendix A) to the end that the inventions of the Licensed Patents will be utilized to provide Licensed Products and/or Licensed Processes for sale in the retail market within the Licensed Field; and
- (c) it will diligently develop markets for Licensed Products and Licensed Processes;
- (d) and, until the date of first commercial sale of Licensed Products or Licensed Processes, it will supply Licensor with a written Development Report annually fifteen (15) days after the end of the calendar year (see Appendix B).

- 3.1.2 Licensee agrees that the first commercial sale of products to the retail customer shall occur on or before July 1, 2027 or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3 hereto. In addition, Licensee will meet the milestones shown in Appendix D or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3. Licensee will notify Licensor in writing as each milestone is met.
- 3.1.3 Upon written request by Licensee to negotiate extensions of any milestones or due dates set forth in Appendix D, such request to be received by Licensor no less than ninety (90) days prior to any of the due dates subject of such request, set forth in this Section 3.1.3, such request fully describing Licensee's diligent efforts to achieve the milestone required to be met by such due date, Licensor shall consider in good faith such requests. Upon granting such request, Licensor and Licensee shall negotiate such extensions in good faith.
- 3.1.4 Licensor's policies may require approval of clinical trials involving technology invented by Licensor. Accordingly, Licensee will notify Licensor prior to commencing any clinical trials at the Licensor's facility or any affiliated medical facilities.
- 3.1.5 Every year Licensor is required to report on statistics that are relevant to growth of businesses in Florida. On January 31 and July 31 of each year, Licensee shall provide a report that includes: the current # of employees in Florida, the total # of employees, information about whether the company has gone public or been acquired, detail of the amount and sources of funding, any new products that have been introduced to the market, the number of employees who are USF graduates, and the number of USF interns for the period since the last report was received. This information will be held in confidence and provided in the aggregate. No confidential information will be identified with the specific company absent your agreement.

#### **Section 4      Payments**

##### **4.1      License Issue Fee.**

Licensee agrees to pay Licensor a License Issue Fee of One Hundred Seventy Thousand Dollars (\$170,000.00) due upon the Effective Date. The first Forty Thousand Dollars (\$40,000.00) is payable no later than July 31, 2018. The remaining One Hundred and Thirty Thousand (\$130,000.00) is due on or before October 31, 2018.

##### **4.2      Issuance of Equity.**

As further consideration for the rights granted to Licensee by this Agreement, as of the Effective Date, Licensee will issue to Licensor that number of shares of common stock of Licensee equal to one percent (1%) of the total number of issued and outstanding shares of Licensee on the Effective Date, according to the terms in Exhibit E, Equity Agreement.



- (a) If the company proposes to sell any equity securities or securities that are convertible into equity securities of the Company (collectively "Equity Securities") in a financing, then RESEARCH FOUNDATION and/or its Assignee (as defined below) will have the right to purchase up to that portion of the Equity Securities that equals the RESEARCH FOUNDATION'S then current, fully-diluted percentage ownership of the Company on the same terms and conditions as are offered with respect to such Equity Securities sold in such financing. The term "Assignee" means (a) any equity to which the RESEARCH FOUNDATION's preemptive rights have been assigned either by the RESEARCH FOUNDATION or another entity, or (b) any entity that is controlled by the University of South Florida or RESEARCH FOUNDATION; and
- (b) If the RESEARCH FOUNDATION and/or its Assignee has no current ownership of the Company, if the Company proposes to sell any Equity Securities, then RESEARCH FOUNDATION and/or its Assignee will have the right to purchase two percent (2%) of the securities issued in such offering on the same terms and conditions as are offered to the other purchasers in such financing.

#### 4.3 Royalty.

**Royalty on Licensed Patents.** In addition to the Section 4.1 License Issue Fee, Licensee agrees to pay to Licensor as earned royalties a royalty calculated as a percentage of Net Sales. The royalty is deemed earned as of the earlier of the date the Licensed Product and/or Licensed Process is actually sold and paid for, the date an invoice is sent by Licensee, it's Affiliate, or it's Sublicensee, or the date a Licensed Product and/or Licensed Process is transferred to a third party for any promotional reasons. Licensee shall pay to Licensor royalties as follows:

- (a) three percent (3%) for Net Sales of Licensed Products, for each product, on a country-by-country basis, as defined by Sections 1.7.1 (a), and 1.7.1(b); and
- (b) three percent (3%) for Net Sales of Licensed Processes, for each process, on a country-by-country basis, as defined by Section 1.7.2 (a); and
- (c) three percent (3%) for Net Sales of all other Licensed Products and Licensed Processes.

#### 4.4 Other Payments.

4.4.1 Licensee agrees to pay Licensor minimum royalty payments, as follows:

Payment	Year
\$ 15,000.00	2023
\$ 30,000.00	2024
\$ 50,000.00	2025; and every year thereafter, for the life of this Agreement.

The minimum royalty shall be paid in advance on a quarterly basis for each year in which this Agreement is in effect. The first minimum royalty payment shall be due on December 31, 2022 and shall be in the amount of Five Thousand Dollars (\$5,000.00). The minimum royalty for a given year shall be due in advance and shall be paid in quarterly installments on March 31, June 30, September 30, and December 31 for the following quarter. Any minimum royalty paid in a calendar year will be credited against the earned royalties for that calendar year. It is understood that the minimum royalties will be applied to earned royalties on a calendar year basis, and that sales of Licensed Products and/or Licensed Processes requiring the payment of earned royalties made during a prior or subsequent calendar year shall have no effect on the annual minimum royalty due Licensor for other than the same calendar year in which the royalties were earned.

4.4.2 In addition to all other payments required under this Agreement, Licensee agrees to pay Licensor milestone payments, as follows:

Payment	Event
\$30,000.00	Upon First Pre-IND Meeting
\$50,000.00	Upon IND Filing
\$150,000.00	Upon first dosing of a patient in a clinical trial
\$400,000.00	Upon Completion of First Phase Clinical Trial
\$1,000,000.00	Upon first patient treated in a Phase III Clinical Trial
\$8,000,000.00	Upon FDA Approval

Sublicenses. In respect to Sublicenses granted by Licensee under 2.2.1 above, Licensee shall pay to Licensor an amount equal to what Licensee would have been required to pay to Licensor had Licensee sold the amount of Licensed Product or Licensed Process sold by such Sublicensee. In addition, if Licensee receives any fees, minimum royalties, milestone payments, or other payments arising from the Sublicense, and such payments are not earned royalties as defined in Section 4.3 above, then Licensee shall pay Licensor fifty percent (50%) of such payments within thirty (30) days of receipt thereof. Such payments shall not be allocated, off-set or otherwise reduced as a result of including rights other than those licensed hereunder in such permitted written Sublicense. Licensee shall not receive from Sublicensees anything of value in lieu of cash payments in consideration arising from any Sublicense under this Agreement without the express prior written permission of Licensor.

4.5 Accounting for Payments.

- 4.5.1 Amounts owing to Licensor under Section 4.3 shall be paid on a quarterly basis after the amount of minimum royalties paid is exceeded, with such amounts due and received by Licensor on or before the thirtieth day following the end of the calendar quarter ending on March 31, June 30, September 30 or December 31 in which such amounts were earned. All royalties owing with respect to Net Sales stated in currencies other than U.S. dollars shall be converted at the rate shown in the Federal Reserve Noon Valuation - Value of Foreign Currencies on the day preceding the payment due date.
- 4.5.2 Any amounts which remain unpaid after the date they are due to Licensor shall accrue interest from the due date at the rate of 1.5% per month. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. Licensee shall also be responsible for repayment to Licensor of any attorney, collection agency, or other out-of-pocket Licensor expenses required to collect overdue payments due under this Section 4 or any other applicable Section of this Agreement.

- 4.5.3 Except as otherwise directed, all amounts owing to Licensor under this Agreement shall be paid in U.S. dollars to Licensor at the following address:
- USF Research Foundation  
Attn: Business Manager  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612.
- 4.5.4 A certified full accounting statement showing how any amounts payable to Licensor under Section 4 have been calculated shall be submitted to Licensor on the date of each such payment. In addition to being certified, such accounting statements shall contain a written representation signed by an executive officer of Licensee that states that the statements are true, accurate, and fairly represent all amounts payable to Licensor pursuant to this Agreement. For earned royalties, such accounting shall be on a per-country and product line, model or trade name basis and shall be summarized on the form shown in Appendix C – Licensor Royalty Report of this Agreement. For earned royalties, in the event no payment is owed to Licensor because the amount of minimum royalties paid has not been exceeded or otherwise, an accounting demonstrating that fact shall be supplied to Licensor.
- 4.5.5 Licensor is exempt from paying income taxes under U.S. law. Therefore, all payments due under this Agreement shall be made without deduction for taxes, assessments, or other charges of any kind which may be imposed on Licensor by any government outside of the United States or any political subdivision of such government with respect to any amounts payable to Licensor pursuant to this Agreement. All such taxes, assessments, or other charges shall be assumed by Licensee.

## **Section 5**

### **Certain Warranties and Disclaimers of Licensor**

- 5.1 Licensor warrants that, except as otherwise provided under Section 17.1 of this Agreement with respect to U.S. Government interests, it is the owner or exclusive licensee of the Licensed Patents or otherwise has the right to grant the licenses granted to Licensee in this Agreement. However, nothing in this Agreement shall be construed as:
- (a) a warranty or representation by Licensor as to the validity or scope of any right included in the Licensed Patents; or
  - (b) a warranty or representation that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will or will not infringe patents of third parties; or
  - (c) an obligation to bring or prosecute actions or suits against third parties for infringement of Licensed Patents; or
  - (d) an obligation to furnish any services other than those specified in this Agreement; or
  - (e) a warranty or representation by Licensor that it will not grant licenses to others to make, use or sell products not covered by the claims of the Licensed Patents which may be similar and/or compete with products made or sold by Licensee.
- 5.2 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, LICENSOR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENT RIGHTS CLAIMS, ISSUED OR PENDING. LICENSOR ASSUMES NO RESPONSIBILITIES WHATSOEVER WITH RESPECT TO USE, SALE, OR OTHER DISPOSITION BY LICENSEE, ITS SUBLICENSEE(S), OR THEIR VENDEES OR OTHER TRANSFEREES OF PRODUCT INCORPORATING OR MADE BY USE OF INVENTIONS LICENSED UNDER THIS AGREEMENT.

## **Section 6**      **Record Keeping**

- 6.1      Licensee and its Sublicensee(s) shall keep books and records sufficient to verify the accuracy and completeness of Licensee's and its Sublicensee(s)'s accounting referred to above, including without limitation, inventory, purchase and invoice records, manufacturing records, sales analysis, general ledgers, financial statements, and tax returns relating to the Licensed Products and/or Licensed Processes. Such books and records shall be preserved for a period not less than six years after they are created or as required by federal law, both during and after the term of this Agreement.
- 6.2      Licensee and its Sublicensee(s) shall take all steps necessary so that Licensor may, within thirty (30) days of its written request, audit, review and/or copy all of the books and records at a single U.S. location to verify the accuracy of Licensee's and its Sublicensee(s)'s accounting. Such review may be performed by any authorized employees of Licensor as well as by any attorneys and/or accountants designated by Licensor, upon reasonable notice and during regular business hours. If a deficiency with regard to any payment hereunder is determined, Licensee and its Sublicensee(s) shall pay the deficiency within thirty (30) days of receiving notice thereof along with applicable interest as described in Section 4.5.12. If a royalty payment deficiency for a calendar year exceeds three percent (3%) of the royalties paid for that year, then Licensee and its Sublicensee(s) shall be responsible for paying Licensor's out-of-pocket expenses incurred with respect to such review.
- 6.3      At any time during the term of this Agreement, Licensor may request in writing that Licensee verify the calculation of any past payments owed to Licensor through the means of a self-audit. Within ninety (90) days of the request, Licensee shall complete a self-audit of its books and records to verify the accuracy and completeness of the payments owed. Within thirty (30) days of the completion of the self-audit, Licensee shall submit to Licensor a report detailing the findings of the self-audit and the manner in which it was conducted in order to verify the accuracy and completeness of the payments owed. If Licensee has determined through its self-audit that there is any payment deficiency, Licensee shall pay Licensor the deficiency along with applicable interest under Section 4.5.1 with the submission of the self-audit report to Licensor.

## **Section 7**      **Patent Prosecution**

- 7.1      Licensor shall prosecute and maintain the Licensed Patents using counsel of its choice. Licensor shall provide Licensee with copies of all documents sent to and received from the United States Patent and Trademark Office and foreign patent offices relating to Licensed Patents. Licensee agrees to keep such information confidential.
- 7.2      Licensee shall pay to Licensor the sum of Forty-One Thousand Four Hundred Twenty-Eight Dollars and Eighty-Nine Cents (\$41,428.89) to reimburse any and all expenses associated with preparation, filing, prosecution, issuance, maintenance, defense, and reporting of the Licensed Patents incurred prior to the Effective Date. This sum is payable in two payments with the first payment of 16,428.89 payable to Licensor within thirty (30) days of the Effective Date. The remaining \$25,000 will be paid to Licensor no later than 4 months from the Effective Date. (**NOTE:** the above referenced dollar amount in this Section 7.2 is subject to change, as all related patent prosecution expense invoices may not have been received from the law firm at the time of license terms negotiation.)

- 7.3 Licensee shall be responsible for and pay all costs and expenses incurred by Licensor related to the preparation, filing, prosecution (including interferences), issuance, maintenance, defense (including oppositions) and reporting of the Licensed Patents subsequent to and separate of those expenses cited in Section 7.2 within thirty (30) days of receipt of an invoice from Licensor. It shall be the responsibility of Licensee to keep Licensor fully apprised of the "small entity" status of Licensee and all Sublicensees with respect to the U.S. patent laws and with respect to the patent laws of any other countries, if applicable, and to inform Licensor of any changes in writing of such status, within thirty (30) days of any such change. In the event that additional licenses are granted to licensees for alternate fields-of-use, patent expenses associated with Licensed Patents will be divided proportionally between the number of existing licensees. In the case of foreign patent protection, if Licensee gives sixty (60) days' notice that it intends to decline to reimburse Licensor for patent expenses for any Licensed Patent in any particular country, then the license granted hereunder respecting such Licensed Patent shall terminate after such sixty (60) days and Licensee relinquishes the right to commercialize Licensed Products in the specified country.

## **Section 8      Infringement and Invalidity**

- 8.1 Licensee shall inform Licensor promptly in writing of any alleged infringement of the Licensed Patents by a third party and of any available evidence thereof.
- 8.2 During the term of this Agreement, Licensor shall have the right, but shall not be obligated, to prosecute at its own expense any such infringements of the Licensed Patents. If Licensor prosecutes any such infringement, Licensee agrees that Licensor may include Licensee as a co-plaintiff in any such suit, without expense to Licensee.
- 8.3 If within six (6) months after having been notified of any alleged infringement, Licensor shall have been unsuccessful in persuading the alleged infringer to desist and shall not have brought an infringement action against the alleged infringer, or if Licensor shall notify Licensee at any time prior thereto of its intention not to bring suit against the alleged infringer, then, and in those events only, Licensee shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Licensed Patents, and Licensee may, for such purposes, use the name of Licensor as party plaintiff. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Licensor, which consent shall not be unreasonably withheld. Licensee shall indemnify Licensor against any order for costs that may be made against Licensor in such proceedings.
- 8.4 In the event that a declaratory judgment action is brought against Licensor or Licensee by a third party alleging invalidity, unpatentability, unenforceability, or non-infringement of the Licensed Patents, Licensor, at its option, shall have the right within twenty (20) days after commencement of such action to take over the sole defense of the action at its own expense. If Licensor does not exercise this right, Licensee shall be responsible for the sole defense of the action at Licensee's sole expense, subject to Sections 8.5 and 8.6.
- 8.5 In the event that Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, Licensor shall have the right, but not the obligation, to voluntarily join such litigation, represented by its own counsel at its own expense. In the event that Licensor or Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by Licensor or Licensee for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of Licensor relating to the suit, and next toward reimbursement of any unreimbursed expenses and legal fees of Licensee relating to the suit. The balance remaining from any such recovery shall be divided equally between Licensee and Licensor.

- 8.6 In any suit in which either party is involved to enforce or defend the Licensed Patents pursuant to this Agreement, the other party hereto shall, at the request and expense of the party initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify if requested, and make available relevant records, papers, information, samples, specimens, and the like.
- 8.7 In the event Licensee contests the validity of any Licensed Patents, unless and until Licensor terminates this Agreement pursuant to 9.3.10, Licensee shall continue to pay royalties and make other payments pursuant to this Agreement with respect to the contested Licensed Patent(s) as if such contest were not underway until the contested Licensed Patent(s) is adjudicated invalid or unenforceable by a court of last resort.

## **Section 9**

### **Term and Termination**

- 9.1 The term of this license shall begin on the Effective Date of this Agreement and continue until the later of the date that no Licensed Patent remains a pending application or an enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, on a country by country basis, or the date on which Licensee's obligation to pay royalties expires pursuant to Section 4.3 above.
- 9.2 Licensee may terminate this Agreement at any time by giving at least sixty (60) days written notice of such termination to Licensor. Such a notice shall be accompanied by a statement of the reasons for termination.
- 9.3 Licensor may terminate this Agreement if (a) Licensee (i) is delinquent on any report or payment; (ii) is not diligently developing and commercializing Licensed Products and Licensed Processes; (iii) misses a milestone described in Appendix D; (iv) is in breach of any provision; (v) provides any false report; (vi) goes into bankruptcy, liquidation or proposes having a receiver control any assets; (vii) violates any laws or regulations of applicable government entities; or (viii) shall cease to carry on its business pertaining to Licensed Patents; or (b) if payments of earned royalties under Section 4.3, once begun, cease for more than two (2) calendar quarters. Termination under this Section 9.3 will take effect 30 days after written notice by Licensor, unless Licensee remedies the problem in that 30-day period, except that termination under Section 9.3 (vi) will occur immediately and automatically upon the occurrence of the event and require no action by Licensor.
- 9.4 If Licensee or any of its Affiliates brings a Patent Challenge against Licensor or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may immediately terminate this Agreement and/or the license granted hereunder. If a Sublicensee brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may send a written demand to Licensee to terminate such Sublicense. If Licensee fails to so terminate such Sublicense within forty-five (45) days after Licensor's demand, Licensor may immediately terminate this Agreement and/or the license granted hereunder.
- 9.5 If Licensee, any of its Affiliates or a Sublicensee (i) brings a Patent Challenge against Licensor or (ii) assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), and if Licensor does not choose to exercise its rights to terminate this Agreement pursuant to Section 9.4 then, in the event that such the Patent Challenge is successful, Licensee will have no right to recoup any consideration, including royalties, paid during the period of challenge. In the event that the Patent Challenge is unsuccessful, Licensee shall reimburse Licensor for all reasonable legal fees and expenses incurred in its defense against the Patent Challenge.

- 9.6 Licensors may immediately terminate this Agreement upon the occurrence of the second separate default by Licensee within any consecutive three-year period for failure to pay royalties, patent or any other expenses when due.
- 9.7 Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. Licensee shall remain obligated to provide an accounting for and to pay royalties earned to the date of termination, and any minimum royalties shall be prorated as of the date of termination by the number of days elapsed in the applicable calendar year. Licensee may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that Licensee shall remain obligated to provide an accounting for and to pay running royalties thereon.
- 9.8 Licensee shall be obligated to deliver to Licensors, within ninety days of the date of termination of this agreement, complete and unredacted copies of all documentation prepared for or submitted for all regulatory approvals of Licensed Products or Licensed Processes.

#### **Section 10**     **Assignability**

This Agreement may not be transferred or assigned by Licensee except with the prior written consent of Licensors, in which case assignee assumes all responsibilities under this license.

#### **Section 11**     **Dispute Resolution Procedures**

##### **11.1**     Mandatory Procedures.

In the event either party intends to file a lawsuit against the other with respect to any matter in connection with this Agreement, compliance with the procedures set forth in this Section shall be a condition precedent to the filing of such lawsuit, other than for injunctive relief. Either party may terminate this Agreement as provided in this Agreement without following the procedures set forth in this section.

- 11.1.1 When a party intends to invoke the procedures set forth in this section, written notice shall be provided to the other party. Within thirty (30) days of the date of such notice, the parties agree that representatives designated by the parties shall meet at mutually agreeable times and engage in good faith negotiations at a mutually convenient location to resolve such dispute.
- 11.1.2 If the parties fail to meet within the time period set forth in section 11.1.1 above or if either party subsequently determines that negotiations between the representatives of the parties are at an impasse, the party declaring that the negotiations are at an impasse shall give notice to the other party stating with particularity the issues that remain in dispute.
- 11.1.3 Not more than 15 days after the giving of such notice of issues, each party shall deliver to the other party a list of the names and addresses of at least three individuals, any one of whom would be acceptable as a neutral advisor in the dispute (the "Neutral Advisor") to the party delivering the list. Any individual proposed as a Neutral Advisor shall have experience in determining, mediating, evaluating, or trying intellectual property litigation and shall not be affiliated with the party that is proposing such individual.

11.1.4 Within 10 days after delivery of such lists, the parties shall agree on a Neutral Advisor. If they are unable to so agree within that time, within 5 days, they shall each select one individual from the lists. Within 5 days, the individuals so selected shall meet and appoint a third individual from the lists to serve as the Neutral Advisor. Within 30 days after the selection of a Neutral Advisor:

- (a) The parties shall each provide a written statement of the issues in dispute to the Neutral Advisor; and
- (b) The parties shall meet with the Neutral Advisor in Tampa, Florida on a date and time established by the Neutral Advisor. The meeting must be attended by persons authorized to make final decisions on behalf of each party with respect to the dispute. At the meeting, each party shall make a presentation with respect to its position concerning the dispute. The Neutral Advisor will then discuss the issues separately with each party and attempt to resolve all issues in the dispute. At the meeting, the parties will enter into a written settlement agreement with respect to all issues that are resolved. Such settlement agreement shall be final and binding with respect to such resolved issues and may not be the subject of any lawsuit between the parties, other than a suit for enforcement of the settlement agreement.

11.1.5 The expenses of the neutral advisor shall be shared by the parties equally. All other out-of-pocket costs and expenses for the alternative dispute resolution procedure required under this Section shall be paid by the party incurring the same.

11.1.6 Positions taken and statements made during this alternative dispute resolution procedure shall be deemed settlement negotiations and shall not be admissible for any purpose in any subsequent proceeding.

11.2 Failure to Resolve Dispute.

If any issue is not resolved at the meeting with the Neutral Advisor, either party may file appropriate administrative or judicial proceedings with respect to the issue that remains in dispute. No new issues may be included in the lawsuit without the mandatory procedures set forth in this section having first been followed.

**Section 12 Product Liability: Conduct of Business**

- 12.1 Licensee and its Sublicensee(s) shall, at all times during the term of this Agreement and thereafter, indemnify, defend and hold Licensor, its board, University and its Affiliates and Trustees, the Florida Board of Governors, and each of their directors, officers, employees, and agents, and the inventors of the Licensed Patents, regardless of whether such inventors are employed by Licensor at the time of the claim, harmless against all claims and expenses, including legal expenses and reasonable attorneys' fees, whether arising from a third party claim or resulting from Licensor's enforcing this indemnification clause against Licensee, arising out of the death of or injury to any person or persons or out of any damage to property and against any other claim, proceeding, demand, expense and liability of any kind whatsoever (other than patent infringement claims) resulting from the development, production, manufacture, sale, use, lease, consumption, marketing, or advertisement of Licensed Products or Licensed Process(es) or arising from any right or obligation of Licensee hereunder. Notwithstanding the above, Licensor at all times reserves the right to retain counsel of its own to defend Licensor's, its board, University and its Affiliates' and Trustees, the Florida Board of Governors', and the inventor's interests.



- 12.2 Licensee warrants that it now maintains and will continue to maintain liability insurance coverage appropriate to the risk involved in development, producing, manufacturing, clinical trials, selling, marketing, using, leasing, consuming, or advertising the products subject to this Agreement and that such insurance coverage lists Licensor, its Affiliates, its Trustees, the Florida Board of Governors, and the inventors of the Licensed Patents as additional insureds. Within ninety (90) days after the execution of this Agreement and thereafter annually between January 1 and January 31 of each year, Licensee will present evidence to Licensor that the coverage is being maintained with Licensor, University and its Affiliates and Trustees, the Florida Board of Governors, and its inventors listed as additional insureds. In addition, Licensee shall provide Licensor with at least thirty (30) days prior written notice of any change in or cancellation of the insurance coverage.

**Section 13** **Use of Names**

Licensee and its Sublicensee(s) shall not use the names of Licensor, nor of any of either institution's employees, agents, or affiliates, nor the name of any inventor of Licensed Patents, nor any adaptation of such names, in any promotional, advertising or marketing materials or any other similar form of publicity, or to suggest any endorsement by the such entities or individuals, without the prior written approval of Licensor in each case.

**Section 14** **Miscellaneous**

- 14.1 This Agreement shall be construed in accordance with the internal laws of the State of Florida
- 14.2 The parties hereto are independent contractors and not joint venturers or partners.
- 14.3 Licensee shall ensure that it applies patent markings that meet all requirements of U.S. law, 35 U.S.C. §287, with respect to all Licensed Products subject to this Agreement.
- 14.4 This Agreement constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, shall vary or modify the written terms of this Agreement. Neither party shall claim any amendment, modification, or release from any provisions of this Agreement by mutual agreement, acknowledgment, or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Agreement.
- 14.5 Licensee shall not encumber or otherwise grant a security interest in any of the rights granted hereunder to any third party.
- 14.6 Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Contract Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant agency of the U.S. Government or written assurances by Licensee that it shall not export such items to certain foreign countries without prior approval of such agency. Licensor neither represents that a license is or is not required or that, if required, it shall be issued.
- 14.7 Licensee is responsible for any and all wire/bank fees associated with all payments due to Licensor pursuant to this agreement.

14.8 Survival.

The provisions of this Section shall survive termination of this Agreement. Upon termination of the Agreement for any reason, the following sections of the License Agreement will remain in force as non-cancelable obligations:

- Section 6 Record Keeping
- Section 9 Requirement to pay royalties on sale of Licensed Products made, and in process, at time of License Agreement termination
- Section 12 Product Liability; Conduct of Business
- Section 13 Use of Names
- Section 18 Confidentiality

**Section 15** **Notices**

Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given (a) when delivered personally; or (b) if sent by facsimile transmission, when receipt thereof is acknowledged at the facsimile number of the recipient as set forth below; or (c) the second day following the day on which the notice has been delivered prepaid to a national air courier service; or five (5) business days following deposit in the U.S. mail if sent certified mail, (return receipt acknowledgement is not required to certify delivery).

15.1 All payments and royalty reports to:

USF Research Foundation  
Attn: Business Manager  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612

Development reports; updates; equity agreements, proxy statements and shareholder information; and all other notices and communications to:

USF Technology Transfer Office/Patents & Licensing  
Attn: Associate Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612

15.2 If to Licensee:

Alzamend Neuro, Inc.  
Attn: CEO  
50 W Broadway, Suite #300  
Salt Lake City, Utah 84101

**Section 16** **Contract Formation and Authority**

The submission of this Agreement does not constitute an offer, and this document shall become effective and binding only upon the execution by duly authorized representatives of both Licensee and Licensor. Copies of this Agreement that have not been executed and delivered by both Licensor and Licensee shall not serve as a memorandum or other writing evidencing an agreement between the parties. This Agreement shall automatically terminate and be of no further force and effect, without the requirement of any notice from Licensor to Licensee, if Licensor does not receive the License Issue Fee or certificates representing shares issued to Licensor pursuant to this Agreement, as applicable, within thirty (30) days of the Effective Date.

- 16.1 Licensor and Licensee hereby warrant and represent that the persons signing this Agreement have authority to execute this Agreement on behalf of the party for whom they have signed.
- 16.2 Force Majeure.

No default, delay, or failure to perform on the part of Licensee or Licensor shall be considered a default, delay or failure to perform otherwise chargeable hereunder, if such default, delay or failure to perform is due to causes beyond either party's reasonable control including, but not limited to: strikes, lockouts, or inactions of governmental authorities, epidemics, war, embargoes, fire, earthquake, hurricane, flood, acts of God, or default of common carrier. In the event of such default, delay or failure to perform, any date or times by which either party is otherwise scheduled to perform shall be extended automatically for a period of time equal in duration to the time lost by reason of the excused default, delay or failure to perform.

#### **Section 17**     **United States Government Interests**

- 17.1 It is understood that the United States Government (through any of its agencies or otherwise) has funded research during the course of or under which any of the inventions of the Licensed Patents were conceived or made. The United States Government is entitled, as a right, under the provisions of 35 U.S.C. §202-212 and applicable regulations of Title 37 of the Code of Federal Regulations, to a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the inventions of such Licensed Patents for governmental purposes. Any license granted to Licensee in this Agreement shall be subject to such right.
- 17.2 Licensee agrees that for Licensed Products covered by the Licensed Patents that are subject to the non-exclusive royalty-free license to the United States Government, said Licensed Products will be manufactured substantially in the United States. Licensee further agrees that it shall abide by all the requirements and limitations of U.S. Code, Title 35, Chapter 18, and implementing regulations thereof, for all patent applications and patents invented in whole or in part with federal money.

#### **Section 18**     **Confidentiality**

Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, Sublicensees or agents. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section 18 shall extend for a period of five (5) years from termination or expiration of this Agreement.

**Section 19      University Rules and Regulations**

Licensee understands and agrees that Licensor's personnel who are engaged by Licensee, whether as consultants, employees or otherwise, or who possess a material financial interest in Licensee, are subject to Florida's rule regarding outside activities and financial interests set forth in Florida Administrative Code Rule 6C1-1.011, the Licensor's Intellectual Property Policy, and a monitoring plan which addresses conflicts of interests associated therewith. Any term or condition of an agreement between Licensee and such personnel which seeks to vary or override such personnel's obligations to Licensor may not be enforced against such personnel or the Licensor, without the express written consent of an individual authorized to vary or waive such obligations on behalf of the Licensor. Furthermore, should an interest of Licensee conflict with the interest of the Licensor, Licensor's personnel are obligated to resolve such conflicts according to the guidelines and policies set forth by the Licensor.

*Signature Page Follows*

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement on the dates indicated below.

**UNIVERSITY OF SOUTH FLORIDA RESEARCH FOUNDATION, INC.**

\_\_\_\_\_, Date: \_\_\_\_\_, 2018

Valerie Landrio McDevitt, Associate Vice President  
Technology Transfer Office

**ALZAMEND NEURO, INC.**

\_\_\_\_\_, Date: July 18, 2018

Philip E. Mansour, President and CEO

**ACKNOWLEDGED AND AGREED:**

**UNIVERSITY OF SOUTH FLORIDA BOARD OF  
TRUSTEES A PUBLIC BODY CORPORATE**

**INVENTOR**

\_\_\_\_\_  
**Keith Anderson, Director**

\_\_\_\_\_  
**Dr. Roland (Doug) Shytle**

**Schedule I**

United States Patent No. 9,840,521, entitled "Organic Anion Lithium Ionic Cocrystal Compounds and Compositions", filed 09/24/2015 and granted 12/12/2017.

## Appendix A - Development Plan

### I. Development Program

#### A. Development activities to be undertaken

1. Continue with Reg A+ funding strategy already in place.
2. By October 1, 2018, contract with a clinical research organization (CRO) to prepare IND package and plan first trial.
3. By January 1, 2019 identify and contract the GMP manufacturer for clinical grade LiSPro.

#### B. Estimated total development time – Achieve FDA approval by July 1, 2026

### II. Governmental Approval – FDA timeline

Due Date	Event
November 1, 2019	Pre-IND Meeting
6 months from Pre-IND Meeting	IND filing
12 months from IND filing	First dosing of a patient in a clinical trial
12 months from completion of the first dosing of a patient	Completion of first clinical trial
12 months from completion of the first Phase II Clinical Trial	First patient treated in a Phase III Clinical Trial
8 years from the Effective Date of this Agreement	FDA Approval

### III. Anticipated date of product launch – July 1, 2027

## **Appendix B - Development Report**

When appropriate, indicate estimated start date and finish date for activities.

- I. Date Development Plan Initiated and Time Period Covered by this Report.
- II. Development Report (4-8 paragraphs).
  - A. Activities completed since last report including the object and parameters of the development, when initiated, when completed and the results.
  - B. Activities currently under investigation, i.e., ongoing activities including object and parameters of such activities, when initiated, and projected date of completion.
- III. Future Development Activities (4-8 paragraphs).
  - A. Activities to be undertaken before next report including, but not limited to, the type and object of any studies conducted and their projected starting and completion dates.
  - B. Estimated total development time remaining before a product will be commercialized.
- IV. Changes to Initial Development Plan (2-4 paragraphs).
  - A. Reasons for change.
  - B. Variables that may cause additional changes.
- V. Items to be Provided if Applicable:
  - A. Information relating to Licensed Products or Licensed Processes that has become publicly available, e.g., published articles, competing products, patents, etc.
  - B. Development work being performed by third parties, other than Licensee, to include name of third party, reasons for use of third party, planned future uses of third parties including reasons why and type of work.
  - C. Update of competitive information trends in industry, government compliance (if applicable) and market plan.
  - D. Information and copies of relevant materials evidencing the status of any patent applications or other protection relating to Licensed Products, or Licensed Processes or the Licensed Patents.

### **PLEASE SEND DEVELOPMENT REPORTS TO:**

USF Division of Patents & Licensing  
Attn: Associate Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612



**Appendix C - Licensor Royalty Report**

**Licensee:** \_\_\_\_\_  
**Agreement No.:** \_\_\_\_\_  
**Inventor:** \_\_\_\_\_  
**Technology#:** \_\_\_\_\_  
**Period Covered:** \_\_\_\_\_ From:    /    / 2 \_\_\_\_\_ Through:    /    / 2 \_\_\_\_\_  
**Prepared By:** \_\_\_\_\_  
**Date:** \_\_\_\_\_  
**Approved By:** \_\_\_\_\_  
**Date:** \_\_\_\_\_

If license covers several major product lines, please prepare a separate report for each line. Then combine all product lines into a summary report.

**Report Type:** ☐ **Single Product Line Report:** \_\_\_\_\_  
                  ☐ **Multiproduct Summary Report.** Page 1 of \_\_\_\_\_ Pages  
                  ☐ **Product Line Detail.** Line: \_\_\_\_\_ Tradename: \_\_\_\_\_ Page: \_\_\_\_\_  
**Report Currency:** ☐ **U. S. Dollars**      ☐ **Other** \_\_\_\_\_

	Unit	Gross	* Less:	Net	Royalty	Period Royalty Amount	
Country	Sales	\$\$ Sales	Allowances	\$\$ Sales	Rate	This Year	Last Year
U.S.A.							
Canada							
Europe:							
Japan							
Other:							
<b>TOTAL:</b>							

Total Royalty: \_\_\_\_\_ Conversion Rate: \_\_\_\_\_ Royalty in U.S. Dollars: \$ \_\_\_\_\_

The following royalty forecast is non-binding and for Licensor's internal planning purposes only:

Royalty Forecast Under This Agreement:

Next Quarter: \_\_\_\_\_ Q2: \_\_\_\_\_ Q3: \_\_\_\_\_ Q4: \_\_\_\_\_

\* On a separate page, please indicate the reasons for returns or other adjustments if significant.  
Also note any unusual occurrences that affected royalty amounts during this period.  
To assist Licensor's forecasting, please comment on any significant expected trends in sales volume.

**PLEASE SEND ROYALTY REPORTS TO:**

USF Research Foundation  
Attn: Business Manager  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612

#### **Appendix D - Milestones**

1. Licensee has already provided Licensor a preliminary business plan. By January 1, 2019, Licensee will provide Licensor a detailed document covering Licensee's plans as to projected product development, and financial forecasts through the initiation of the Phase III Clinical Trial ("Business Plan"). Licensor will treat this Business Plan as Confidential Information and to protect it as Licensor would its own Confidential Information.
2. By 12 months from the Effective Date, Licensee will have Five Million Dollars \$5,000,000 of available non-contingent, operating capital to proceed with the exploration and development of Licensed Product. Capital will be from a third party who may or may not be an investor in Licensee and unused capital will be on deposit in a financial institution acceptable to both Licensor and Licensee.
3. Company will meet the following Regulatory Milestones:

<b>Due Date</b>	<b>Event</b>
November 1, 2019	Pre-IND Meeting
6 months from Pre-IND Meeting	IND filing
12 months from IND filing	First dosing of a patient in a clinical trial
12 months from completion of the first dosing of a patient	Completion of first clinical trial
12 months from completion of the first Phase II Clinical Trial	First patient treated in a Phase III Clinical Trial
6 years from the Effective Date of this Agreement	FDA Approval

By July 1, 2027, Licensee will have a first sale of Licensed Product.

## **Appendix E - Equity Agreement - USFRF equity**

THIS EQUITY AGREEMENT (the "Equity Agreement") is made effective July 02, 2018 by and between The University of South Florida Research Foundation, Inc. (hereinafter called "Licensor"), a non-stock, nonprofit Florida corporation under Chapter 617 Florida Statutes, and a direct support organization of the University of South Florida ("University") pursuant to section 1004.28 Florida Statutes, and Alzamend Neuro, Inc. (hereinafter called "Licensee"), a corporation organized and existing under the laws of Delaware.

WHEREAS, Licensor and Licensee have entered into a certain License Agreement with respect to certain inventions owned by Licensor or in which Licensor has a joint, undivided interest;

WHEREAS, as an accommodation to Licensee, Licensor is willing to accept shares of common stock of Licensee (the "Shares") in lieu of charging Licensee certain fees under the License Agreements.

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth below, the parties covenant and agree as follows:

### **Section 1      Definitions**

For the purpose of this Agreement, the Exhibit A definitions shall apply. Capitalized terms used and not otherwise defined herein shall have the meanings assigned thereto in the License Agreements.

### **Section 2      Issuance of Shares to USFRF; Closing Deliveries**

#### **2.1      Issuance of Shares**

- 2.1.1      As further consideration for the rights granted to Licensee by this Agreement, as of the Effective Date, (i) Licensee will issue to USFRF that number of shares of common stock of Licensee equal to two percent (2%) of the total number of issued and outstanding shares of Licensee on the Effective Date. If at any time after the Effective Date of this Agreement and before Licensee receives a total of five million Dollars (\$5,000,000.00) cash in exchange for the issuance of (i) Licensee's equity securities and/or (ii) debt securities that are convertible into or exercisable or exchangeable for Licensee's equity securities, Licensee issues any (a) shares of common stock or (b) securities that are convertible into or exercisable or exchangeable for shares of Licensee's common stock, then in such event, Licensee shall issue additional shares of common stock to USFRF such that immediately after such issuance to USFRF the total number of shares issued to USFRF under this Section constitutes two percent (2%) of the total number of issued and outstanding shares of Licensee calculated on a fully diluted basis. Licensee shall deliver, or cause to be delivered, to USFRF a stock certificate, duly signed by appropriate officers of Licensee and issued in USFRF's name, representing all of the Shares required to be issued to USFRF.
- 2.1.2      All Shares shall be fully-paid and non-assessable upon their issuance to USFRF. USFRF's execution of this Agreement and the License Agreements shall be deemed full consideration for the issuance of the Shares, and no additional consideration for such Shares shall be due from USFRF. No Shares shall be subject to any restrictions on their transfer other than the restrictions specified in Exhibit C hereto.

- 2.1.3 If USFRF owns 8% or less of the outstanding shares of common stock of Licensee, or will own 8% or less as a result of an initial public offering by Licensee, USFRF's shares will not be subject to any lock-up requirement or other restriction on selling such shares, other than as required by law, in connection with the initial public offering or any public offering by Licensee thereafter.

No adjustment shall be made under this Section 2 with respect to the issuance of shares (a) to employees, consultants, officers or directors of Licensee pursuant to any bona fide stock option plan of Licensee approved by the Board of Directors, (b) shares issued upon any stock split or stock dividend, (c) shares issued for fair value (as determined in good faith by the Board of Directors) pursuant to the acquisition of any other company by Licensee by merger or purchase of substantially all of the assets or other reorganization.

## 2.2 Closing Deliveries

On the Effective Date, in addition to the certificates evidencing the Shares, Licensee shall deliver to USFRF the following:

- 2.2.1 a certificate from Licensee, dated as of the Effective Date and signed by the Secretary or an Assistant Secretary of Licensee, certifying that the attached copies of the Certificate of Incorporation, Bylaws of Licensee, and resolutions of the Board of Directors of Licensee approving the License Agreements, this Agreement and the transactions contemplated thereby, are all true, complete and correct and that such resolutions remain unamended and in full force and effect.

## **Section 3** Representations and Warranties

### 3.1 Representations and Warranties by Licensee

Licensee represents and warrants to USFRF that:

- 3.1.1 Licensee is a duly organized and validly existing corporation under the laws of the State of Delaware with adequate power and authority to conduct the business in which it is now engaged or currently proposed to be engaged, and Licensee is duly qualified to do business as a foreign corporation and is in good standing in such other states or jurisdictions as is necessary to enable it to carry on its business or own its properties.
- 3.1.2 There are no actions, suits, or proceedings pending or threatened against or affecting Licensee, its officers or directors in their capacity as such, its properties, or its patents in any court or before any governmental or administrative agency, which can have any material adverse effect on the business as now conducted or as currently proposed to be conducted, on the properties, the financial condition, or income of Licensee, or the transactions contemplated by this Agreement or the License Agreements and Licensee is not in default under any order or judgment of any court or governmental or administrative agency.
- 3.1.3 Licensee is not a party to any agreement or instrument, or subject to any charter, bylaw, or other corporate restrictions materially adversely affecting its business and operations, present or prospective, or its property, assets, or condition, financial or otherwise.

- 3.1.4 Licensee is not in default or breach in the performance, observance, or fulfillment of any of the obligations, covenants, or conditions contained in any bond, debenture, note, or other evidence of indebtedness or any contract or other agreement of Licensee.
- 3.1.5 This Agreement has been duly authorized, executed, and delivered on behalf of Licensee and constitutes the valid and binding agreement of Licensee, enforceable in accordance with its terms, and Licensee has full power and lawful authority to issue, sell, and repurchase the Shares on the terms and conditions herein set forth.
- 3.1.6 Consummation of the transactions contemplated by this Agreement in compliance with provisions of this Agreement will not result in any breach of any of the terms, conditions, or provisions of, or constitute a default under, or result in the creation of any lien, charge, or encumbrance on, any property or assets of Licensee pursuant to any indenture, mortgage, deed of trust, agreement, corporate charter, bylaws, contract, or other instrument to which Licensee is a party or by which Licensee may be bound or any law, rule, regulation, qualification, license, order or judgment applicable to Licensee or any of its property.
- 3.1.7 Licensee is in compliance with all federal, state and local environmental laws and there are no conditions currently existing or contemplated which are likely to subject Licensee to damages, penalties, injunctive relief, removal costs, remedial costs or cleanup costs under any such laws or assertions thereof.
- 3.1.8 Attached hereto as Exhibit B and hereby made a part hereof are the Articles of Incorporation (including any amendments thereto) Bylaws (including any amendments thereto) of Licensee in effect on the date hereof.
- 3.1.9 Pursuant to its Articles of Incorporation, Licensee is authorized to issue 310,000,000 Shares (300,000,000 shares of common stock and 10,000,000 shares of preferred stock), of which 49,278,701 Shares are issued and outstanding. All issued and outstanding Shares are, and the Shares issuable to USFRF will be, validly issued, fully paid and nonassessable, and are not subject to any preemptive rights. There are no other authorized or outstanding Equity Securities of any class, kind, or character, and there are no outstanding subscriptions, options, warrants, or other agreements, or commitments obligating Licensee to issue any additional shares of its capital stock of any class, or any options or rights with respect thereto, or any securities convertible into any shares of stock of any class. No person has any preemptive rights, rights of first refusal, "tag along" rights, rights of co-sale or any similar rights with respect to the issuance of the Shares contemplated hereby. **NOTE: This Section 3.1.9 shall be completed based upon information provided by Licensee on or before July 31, 2018.**
- 3.1.10 Attached hereto as Exhibit C and hereby made a part hereof is a list of all restrictions on the transfer of any Shares or other securities of Licensee and all agreements between any shareholders or convertible debt holders of Licensee regarding the valuation, voting or transfer of any Shares or other securities of Licensee.
- 3.1.11 Attached hereto as Exhibit D and hereby made a part hereof are the unaudited Financial Statements of Licensee for the year ended April 30, 2018. These financial statements are true and complete and are in accordance with the books and records of Licensee. As of the date of the most recent financial statements provided to USFRF under this Agreement, Licensee has no material liabilities, absolute or contingent, that are not reflected in such financial statements except obligations incurred in the ordinary course of business and the License Agreements. **NOTE: This Exhibit D shall be provided by Licensee on or before August 31, 2018.**

- 3.1.12 Since the date of the most recent financial statements provided to USFRF under this Agreement, there has been no: (a) material adverse change in the condition, financial or otherwise, of Licensee other than changes in the ordinary course of business; (b) damage or loss, whether or not covered by insurance, materially and adversely affecting Licensee's properties or business taken as a whole; and (c) declaration or setting aside, or payment of any dividend or other distribution in respect of the stock of Licensee or any direct or indirect redemption, purchase or other acquisition of such shares.
- 3.1.13 Licensee has timely filed all tax returns and reports required to be filed by it. Licensee has timely paid all taxes, interest and penalties required to be paid pursuant to said returns or otherwise required to be paid by it.
- 3.1.14 Attached hereto as Exhibit E is a true and complete record of (i) issued and outstanding Shares as of the Effective Date and the holders thereof, and (ii) Shares issuable under options, warrants or other convertible equity or debt instruments outstanding as of the Effective Date, whether vested or non-vested, restricted or unrestricted, the holders thereof, the exercise price or conversion price thereof and an outline of all other material terms with respect thereto.

3.2 Representations and Warranties by USFRF

USFRF represents and warrants to Licensee that:

- 3.2.1 USFRF is acquiring the Shares for investment for its own account and not with a view to resale or distribution within the meaning of the Securities Act, and USFRF does not intend to divide its participation with other or to resell or otherwise dispose of all or any part of the Shares without registration under the Securities Act, except to Licensee or unless and until it determines at some future date that changed circumstances, not now in its contemplation, make such disposition advisable.
- 3.2.2 This Agreement has been duly authorized, executed, and delivered on behalf of USFRF and constitutes the valid and binding agreement of USFRF, enforceable in accordance with its terms, and USFRF has full power and lawful authority to acquire the Shares on the terms and conditions herein set forth.

3.3 Survival and Timing of Warranties

The warranties and representation made in this Section 3 shall survive the closing of any issuance of shares to USFRF. The warranties and representations made in this Section 3 shall be true and correct as of the date of this Agreement and as of the date the Shares are issued to USFRF.

**Section 4** Miscellaneous Covenants

4.1 Financial Statements and Other Information

As long as USFRF owns any Equity Securities, Licensee shall promptly provide to USFRF such Financial Agreements, amendments to or restatements of its Articles of Incorporation or Bylaws, stock transfer restrictions and agreements among shareholders with respect to the valuation, transfer or voting of Shares and amendments thereto as may be effected from time to time, and such other information respecting the business, affairs, and financial condition of Licensee as USFRF may reasonably request. Financial Statements shall be provided within the time that such Financial Statements are required to be provided to holders of preferred stock of Licensee. USFRF's representatives may visit and inspect any of the properties, books and information of Licensee, upon reasonable notice, during business hours and in a manner not disruptive to the business of the Licensee.

#### 4.2 Preemptive Rights

- 4.2.1 In addition to its other rights under this Agreement, USFRF shall have a preemptive right to acquire such Shares or other Equity Securities that may be issued from time to time by Licensee while USFRF remains the owner of any Equity Securities. Such preemptive right shall apply with respect to all Equity Securities issued by Licensee after the Effective Date, whether such additional Equity Securities constitute a part of the Equity Securities presently or subsequently authorized or constitute Equity Securities held in the treasury of Licensee, and regardless of whether such Equity Securities are to be issued for cash, property (other than cash) or services. Such preemptive right shall not apply to (i) Equity Securities issued pursuant to the acquisition of another corporation or business entity by Licensee or one or more of its wholly owned subsidiaries by merger, consolidation, share exchange, purchase of substantially all the assets or other reorganization whereby the shareholders of Licensee immediately prior to the transaction owns in the aggregate more than 50% of the voting power of Licensee or other surviving entity after the transaction; (ii) Equity Securities issued to employees, consultants or directors of Licensee pursuant to any incentive agreement or arrangement approved by the Board of Directors of Licensee; (iii) Equity securities issued pursuant to any stock dividend, stock split, combination or other reclassification by Licensee of any of its capital stock; or (iv) Equity Securities issued in connection with real or personal property leases or loans or lines of credit from financial institutions.
- 4.2.2 In furtherance of the preemptive rights hereby granted USFRF, Licensee agrees to provide USFRF with not less than fifteen (15) days prior written notice (an "Equity Security Issuance Notice") of its intent to issue any Equity Securities. Such notice should specify in reasonable detail the Equity Securities to be issued, including class, total number of shares and the applicable rights and preferences associated therewith, including, if applicable, conversion rights into Shares, and the purchase price for the Equity Securities USFRF may purchase pursuant to its preemptive rights hereby granted. USFRF shall have the right to acquire Equity Securities of the type being issued in an amount equal to USFRF's Proportionate Share Percentage of the aggregate Equity Securities of that type that are to be issued to all persons or entities pursuant to that issuance. The terms and conditions of USFRF's exercise of its preemptive rights, including the consideration to be paid for such Equity Securities, shall be no less favorable to USFRF than the most favorable price, terms and conditions offered to any other shareholder or prospective shareholder with respect to the Equity Securities then being issued.
- 4.2.3 In order to exercise USFRF's preemptive rights, USFRF shall deliver written notice thereof to Licensee within fifteen (15) days following its receipt of the Equity Securities Issuance Notice to which such exercise relates, accompanied by full payment of the purchase price for the Equity Securities to be purchased by USFRF in connection with the exercise of such preemptive rights. USFRF may, at its option, exercise such preemptive rights to some or all of the Equity Securities to which it has preemptive rights under this Section 4.2. In the event that any Equity Securities are to be issued by Licensee in return for property (other than cash) or services, in calculating the purchase price of the Equity Securities with respect to which USFRF has preemptive rights pursuant to this Section 4.2, the purchase price for the Equity Securities to be issued in exchange for non-cash property or services shall be equal to the fair market value of such property or services as determined in good faith by the Board of Directors of Licensee.



4.3 Issuance of Shares/Options to Affiliates/Founders

Licensee shall not issue any Equity Securities (including Shares) to any of the shareholders of Licensee listed on Exhibit A attached hereto (the "Founders"), Affiliate thereof or Affiliate of Licensee for less than the fair market value of that security. Licensee shall have the burden of proving that the consideration to be paid for any such Equity Securities equals the fair market value of such Equity Securities issued.

4.4 Piggyback Registration Rights

- 4.41 At any time after the first anniversary of the date that a registration statement covering an initial public offering of Shares of Licensee becomes effective, as soon as practicable after a written request from USFRF to effect a registration with respect to all or part of the Shares owned by USFRF, Licensee will use its diligent best efforts to effect such Registration, cause it to become effective promptly and maintain it as effective for at least 36 months (or less if all the Shares included therein are sooner sold). If so requested by USFRF, Licensee shall enter into an underwriting agreement in customary form with any underwriter selected by USFRF with respect to such Registration.
- 4.42 If the Licensee proposes to register any of its securities either for its own account or the account of a security holder or holders, other than a registration on any form which does not permit secondary sales, Licensee will promptly give USFRF written notice thereof and include in such Registration (and any related qualification under Blue Sky laws or other applicable laws), and in any underwriting involved therewith, all of the Shares specified in a written request made by USFRF within twenty (20) days after Licensee's written notice to USFRF.
- 4.43 All expenses incurred by Licensee and USFRF in connection with any Registration hereunder, including reasonable fees and disbursements of accountants and counsel for USFRF, but excluding underwriting discounts and commissions and transfer taxes, shall be borne solely by Licensee.
- 4.44 To the extent permitted by law, Licensee will indemnify USFRF and each of its officers, directors, and control persons ("USFRF indemnified parties") against all claims, losses, damages and liabilities ("Claims") arising out of or on any untrue statement (or alleged untrue statement) of a material fact contained in any prospectus or other document incident to any such Registration, or any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading (to the extent not made in reliance upon written information furnished by USFRF specifically for use in such Registration) or any violation by Licensee of the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, and will reimburse each USFRF indemnified party for any legal and other expenses reasonably incurred in connection with investigating and defending or settling any such Claim.

#### 4.5 Rule 144 Reporting

With a view to making available to USFRF the benefits of certain rules and regulations of the Commission which may permit USFRF to sell securities of Licensee to the public without registration, Licensee agrees to:

- 4.5.1 Make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act, at all times following the effective date of the first registration under the Securities Act filed by Licensee for an offering of its securities to the general public;
- 4.5.2 Use its best efforts to file with the Commission in a timely manner all reports and other documents required of Licensee under the Securities Act and the Exchange Act at any time following registration of any of its securities under the Securities Act or Exchange Act; and
- 4.5.3 So long as USFRF owns any Shares, furnish to USFRF forthwith upon request a written statement by Licensee as to its compliance with the reporting requirements of Rule 144 (at any time following the effective date of the first registration statement filed by Licensee for an offering of its securities to the general public), and of the Securities Act and the Exchange Act following registration of any of its securities under the Securities Act or Exchange Act, a copy of the most recent annual or quarterly report of Licensee, and such other reports and documents so filed as USFRF may reasonably request in availing itself of any rule or regulation of the Commission allowing USFRF to sell any such securities without registration.

#### 4.6 Transfer or Assignment of Registration Rights

The rights to cause Licensee to register the securities granted to USFRF hereunder may be transferred or assigned by USFRF to a transferee or assignee of any of USFRF's Shares; *provided, however*, that such transfer or assignment of Shares was permitted under this Agreement.

### **Section 5** Tag-Along Rights

- 5.1 If, at any time, prior to an initial public offering, any of the shareholders set forth on Exhibit E (the "Disposing Shareholders") propose to sell, within a two-year period and in any one or more private transactions, capital stock of Licensee which, in the aggregate, represents more than fifty percent (50%) of the outstanding capital stock of Licensee on a fully-diluted basis to any one or more third parties (a "Third Party"), then USFRF shall have the right to participate (a "Tag-along Right") in such sale with respect to the Shares, on a pro rata basis for the same consideration per share and otherwise on the same terms as the Disposing Shareholders. If circumstances occur which give rise to the Tag-along Right, then the Disposing Shareholders shall give written notice to USFRF, providing the particulars of the proposed sale to the Third Party and advising USFRF of its Tag-along Rights. USFRF may exercise its Tag-along Right by written notice to the Company and the Disposing Shareholders within twenty-five (25) days of the date of mailing of the Disposing Shareholders' notice stating the number of shares that USFRF wishes to sell, up to the maximum permitted herein. If USFRF gives written notice indicating that it wishes to sell, USFRF shall be obligated to sell that number of Shares specified in its written acceptance notice upon the same terms and conditions as the Disposing Shareholders are selling to the Third Party and shall not be subject to the requirements of Section 7. For purposes of this Section 5, "pro rata" means the percentage derived by dividing the aggregate Shares then owned by USFRF by the aggregate Shares then owned by USFRF and the Disposing Shareholders. The Company agrees to cause its shareholders, including those persons who become shareholders from time to time in the future, to enter into an agreement to carry out the provisions of this Section 5.1.

- 5.2 Upon receipt of such notice, Licensee shall tender the specified number of Shares, if any, at the same price applicable to the Transferring Shareholders in the transaction. In each case, tender shall be made upon the same terms and conditions applicable to the Transferring Shareholders in the transaction or, in the discretion of the acquirer or successor to Licensee, upon payment of the purchase price to the Shareholder in immediately available funds.

**Section 6** **Termination**

- 6.1 Unless terminated sooner by either party as provided below, this Agreement shall terminate on the date that USFRF, after having been issued Shares hereunder, no longer owns any Equity Securities. If this Agreement terminates automatically as provided in this Section 6, the License Agreements shall remain in effect according to the terms specified therein.
- 6.2 If Licensee at any time fails to timely issue Shares to USFRF on a timely basis, or otherwise commits a material breach of this Agreement, or if any of the representations or warranties made by Licensee are untrue in any material respect as of any date on which they are required to be true and correct, and Licensee fails to remedy any such breach or default within thirty (30) days after written notice thereof by USFRF, USFRF may, at its option, terminate either this Agreement, the License Agreements, or all of them.

**Section 7** **Assignability**

Except as set forth in Section 4.6, neither party may assign its rights or obligations under this Agreement, except that Licensee may assign this Agreement in connection with the sale of all or substantially all of the assets or stock of the Licensee, whether by merger, acquisition or otherwise, if the successor assumes all of the Licensee's obligations hereunder.

**Section 8** **Miscellaneous**

This Agreement shall be construed exclusively in accordance with the internal laws of the State of Florida.

**Section 9** **Notices**

Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given at the earlier of the time when actually received as a consequence of any effective method of delivery, including but not limited to hand delivery, transmission by telecopier, or delivery by a professional courier service or the time when sent by certified or registered mail addressed to the party for whom intended at the address below or at such changed address as the party shall have specified by written notice, provided that any notice of change of address shall be effective only upon actual receipt:

to Licensor:

USF Division of Patents & Licensing  
Attn: Assistant Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612

with a copy to:

USF Division of Patents & Licensing  
Attn: Assistant Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612

to Licensee:

Alzamend Neuro, Inc.  
Attn: CEO  
50 W Broadway, Suite #300  
Salt Lake City, Utah 84101

**Section 10     Integration**

This Agreement constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, except as provided for elsewhere in this 10, made prior to or at the signing with respect to the subject matter hereof, shall vary or modify the written terms of this Agreement. Neither party shall claim any amendment, modification, or release from any provisions of this Agreement by mutual agreement, acknowledgment or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Agreement.

*Signature Page Follows*

IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement on the dates indicated below.

**THE UNIVERSITY OF SOUTH FLORIDA RESEARCH FOUNDATION, INC.**

\_\_\_\_\_, Date: \_\_\_\_\_, 2018

Valerie Landrio McDevitt, Associate Vice President  
Technology Transfer Office

**ALZAMEND NEURO, INC.**

\_\_\_\_\_, Date: July 18, 2018

Philip E. Mansour, President and CEO

Reviewed by Licensor's Attorney:

\_\_\_\_\_  
(name typed)  
(Attorney shall not be deemed a signatory to this Agreement.)

**Exhibit A - Definitions In Equity Agreement**

- (1) "Shares" shall mean shares of Licensee's common stock, \$.0001 par value per share. **Note: This portion of Exhibit A to be provided by Licensee on or before July 31, 2018**
- (2) "License Agreements" shall mean the LIC18110 license agreements entered into between USFRF and Licensee of even date herewith pertaining to each Licensed Patent Group, as such term is defined in each License Agreement.
- (3) "Affiliate" shall mean any person who is related by blood or marriage to any person or entity who owns more than twenty percent of the issued and outstanding shares of Licensee or to any officer, director, or employee of Licensee or any entity in which any such person has a direct or indirect beneficial ownership interest or for which any such person serves as a director, officer or employee.
- (4) "Financial Statements" shall mean a balance sheet, and the related statements of earnings, stockholders' equity and cash flow as of the end of the last fiscal year that has been completed when the statements are to be provided to USFRF and a balance sheet and income statement as of the end of the last fiscal quarter, which financial statements shall be in the form and delivered at the time that such financial statements are delivered to holders of preferred stock of Licensee. Financial Statements shall be true and complete and prepared in accordance with the books and records of Licensee and with generally accepted accounting principles.
- (5) "Equity Securities" shall mean the Shares, any other capital stock of Licensee (including preferred shares), and any securities of Licensee that are convertible into capital stock of Licensee or that carry a right to subscribe to or acquire capital stock of Licensee.
- (6) "Register," "Registered," and "Registration" shall refer to a registration effected by preparing a filing a Registration Statement in compliance with the Securities Act, and the declaration or ordering of the effectiveness of such Registration Statement.
- (7) "Proportionate Share Percentage" with respect to USFRF, for purposes of Section 4.2, shall mean the percentage derived by dividing the aggregate Shares then owned by USFRF by the total number of issued and outstanding Shares on an as-converted basis at such time.
- (8) "Securities Act" shall mean the Securities Act of 1933, as amended, or any similar federal statute, and the rules and regulations of the Securities and Exchange Commission issued under such act, as they each may, from time to time, be in effect.
- (9) "Commission" shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.
- (10) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

**Exhibit B - Articles of Incorporation and Bylaws**

**Bylaws to be provided by Licensee on or before July 31, 2018**

# Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF INCORPORATION OF "ALEAMEND NEURO, INC.", FILED IN THIS OFFICE ON THE TWENTY-SIXTH DAY OF FEBRUARY, A.D. 2016, AT 3:05 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE NEW CASTLE COUNTY RECORDER OF DEEDS.

5976073 8100  
SR# 20161234328



You may verify this certificate online at [corp.delaware.gov/authver.shtml](http://corp.delaware.gov/authver.shtml)

A handwritten signature in black ink, appearing to read "JBULLOCK", written over a horizontal line.

Authentication: 201900010  
Date: 02-29-16



**CERTIFICATE OF INCORPORATION**

**OF**

**ALZAMEND NEURO, INC.**

State of Delaware  
Secretary of State  
Division of Corporations  
Delivered 4:45 PM 02/26/2016  
FILED 4:45 PM 02/26/2016  
SR 20141234028 - File Number 5974873

**FIRST:** The name of the Corporation is Alzamend Neuro, Inc. (the "Corporation").

**SECOND:** The address of the registered office of the Corporation in the State of Delaware is 2711 Centerville Road, Suite 400, Wilmington, DE 19808, New Castle County. The name of its registered agent at that address is Corporation Service Company.

**THIRD:** The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware as set forth in Title 8 of the Delaware Code (the "DGCL").

**FOURTH:** The Corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Corporation is authorized to issue is 160,000,000 shares. 150,000,000 shares shall be Common Stock, each having a par value of \$0.0001. 10,000,000 shares shall be Preferred Stock, each having a par value of \$0.0001.

The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby expressly authorized to provide for the issue of all or any of the shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board of Directors providing for the issuance of such shares and as may be permitted by the DGCL. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

**FIFTH:** The name and mailing address of the Sole Incorporator is as follows:

<u>Name</u>	<u>Address</u>
<u>Milton C. Ault, III</u>	<u>P.O. Box 3587</u> <u>Tustin, CA 92781</u>

**SIXTH:** The following provisions are inserted for the management of the business and the conduct of the affairs of the Corporation, and for further definition, limitation and regulation of the powers of the Corporation and of its directors and stockholders:

(1) The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

(2) The directors shall have concurrent power with the stockholders to make, alter, amend, change, add to or repeal the Bylaws of the Corporation.

(3) The number of directors of the Corporation shall be as from time to time fixed by, or in the manner provided in, the Bylaws of the Corporation. Election of directors need not be by written ballot unless the Bylaws so provide.

(4 ) No director shall be personally liable to the Corporation or any of its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit. Any repeal or modification of this Article SIXTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification with respect to acts or omissions occurring prior to such repeal or modification.

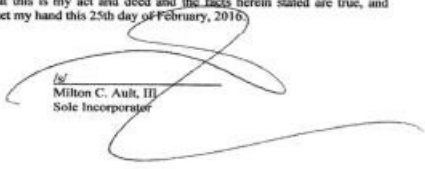
(5) In addition to the powers and authority hereinbefore or by statute expressly conferred upon them, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation, subject, nevertheless, to the provisions of the DGCL, this Certificate of Incorporation, and any Bylaws adopted by the stockholders; provided, however, that no Bylaws hereafter adopted by the stockholders shall invalidate any prior act of the directors which would have been valid if such Bylaws had not been adopted.

**SEVENTH:** Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept (subject to any provision contained in the DGCL) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

**EIGHTH:** The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

\* \* \* \* \*

I, THE UNDERSIGNED, being the Sole Incorporator hereinbefore named, for the purpose of forming a corporation pursuant to the DGCL, do make this Certificate, hereby declaring and certifying that this is my act and deed and the facts herein stated are true, and accordingly have hereunto set my hand this 25th day of February, 2016.

  
Milton C. Ault, III  
Sole Incorporator

**Exhibit C - Stock Restrictions**

(1) Restrictive Legend.

Each certificate representing (i) the Shares and (ii) any other securities issued in respect of the Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event, shall (unless otherwise permitted by the provisions of Section (2) below) be stamped or otherwise imprinted with a legend in substantially the following form (in addition to any legend required under applicable state securities laws).

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO DISTRIBUTION OR RESALE, AND MAY NOT BE SOLD, MORTGAGED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND ANY APPLICABLE STATE SECURITIES LAWS, OR THE AVAILABILITY OF AN EXEMPTION FROM THE REGISTRATION PROVISIONS OF THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

Each holder consents to Licensee's making a notation on its records and giving instructions to any transfer agent of the Shares in order to implement the restrictions on transfer established in this Section (1). Such legend shall be removed by Licensee from any certificate at such time as the holder of the Shares represented by the certificate satisfies the requirements of Rule 144(k) under the Securities Act, provided that Rule 144(k) as then in effect does not differ substantially from Rule 144(k) as in effect as of the date of this Agreement and other applicable regulations do not then require such legend to be included on the Shares, and provided further that Licensee has received from the holder a written representation that (i) such holder is not an Affiliate of Licensee and has not been an Affiliate during the preceding three months, (ii) such holder has beneficially owned the Shares represented by the certificate for a period of at least two years, (iii) such holder otherwise satisfies the requirements of Rule 144(k) as then in effect with respect to such Shares, and (iv) such holder will submit the certificate for any such Shares to Licensee for reapplication of the legend at such time as the holder becomes an Affiliate of Licensee or otherwise ceases to satisfy the requirements of Rule 144(k) as then in effect.

(2) Notice of Proposed Transfers.

The holder of each certificate representing Shares by acceptance thereof agrees to comply in all respects with the provisions of this Section (2). Prior to any proposed sale, assignment, transfer or pledge of Shares, unless there is in effect a registration statement under the Securities Act covering the proposed transfer, the holder thereof shall give written notice to the Licensee of such holder's intention to effect such transfer, sale, assignment or pledge in sufficient detail, and shall be accompanied at such holder's expense by a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Licensee addressed to the Licensee, to the effect that the proposed transfer of the Shares may be effected without registration under the Securities Act. Each certificate evidencing the Shares transferred as above provided shall bear, except if such transfer is made pursuant to Rule 144, the appropriate restrictive legend set forth in Section (1) above, except that such certificate shall not bear such restrictive legend if in the opinion of counsel for such holder and Licensee such legend is not required in order to establish compliance with any provisions of the Securities Act. Prior to any transfer of the Shares in accordance with this Section (2), such transferee shall execute and deliver a form of agreement reasonably acceptable to the Licensee wherein the transferee agrees to be bound by the provisions of this Exhibit C.

(3) Transfer to Competitor.

No holder shall transfer any Shares to a competitor of Licensee, as determined by the Board of Directors of Licensee in good faith. This provision shall terminate after the closing of the sale of Equity Securities of Licensee registers pursuant to a registration statement filed under the Securities Act.

**Exhibit D - Financial Statements**

*To be provided by Licensee on or before August 31, 2018*

**Exhibit E - List of Stockholders and Option Holders**

*To be provided by Licensee on or before July 31, 2018*

**Exhibit F - Form of Opinion**

*To be provided by Licensee on or before July 31, 2018*



**STANDARD EXCLUSIVE LICENSE AGREEMENT**  
**WITH SUBLICENSING TERMS**

Agreement # Number LIC18111.

This Agreement is made effective July 02, 2018, (the "Effective Date") by and between the University of South Florida Research Foundation, Inc. (hereinafter called "Licensor"), a nonstock, nonprofit Florida corporation, under Chapter 617 Florida Statutes, and a direct support organization of the University of South Florida ("University") pursuant to section 1004.28 Florida Statutes and Alzamend Neuro Inc. (hereinafter called "Licensee"), a small corporation organized and existing under the laws of Delaware;

WHEREAS, Licensor is the exclusive licensee of certain inventions that are described in the "Licensed Patents" defined below (Licensor Reference #14B168), and Licensor is willing to grant a license to Licensee under any one or all of the Licensed Patents and Licensee desires a license under all of them;

NOW, THEREFORE, in consideration of the mutual covenants and agreements set forth below, the parties covenant and agree as follows:

**Section 1            Definitions**

- 1.1 "Affiliate" means: (a) any person or entity which controls at least fifty percent (50%) of the equity or voting stock of the Licensee or (b) any person or entity fifty percent (50%) of whose equity or voting stock is owned or controlled by the Licensee or (c) any person or entity of which at least fifty percent (50%) of the equity or voting stock is owned or controlled by the same person or entity owning or controlling at least fifty percent (50%) of Licensee or (d) any entity in which any officer or employee is also an officer or employee of Licensee or any person who is an officer or employee of Licensee or (e) any other relationship as in fact, constitutes actual control.
- 1.2 "Development Plan" means the written report summarizing the development activities that are to be undertaken by the Licensee to bring Licensed Products and/or Licensed Processes to the market. The Development Plan is attached as Appendix A.
- 1.3 "Development Report" means a written account of Licensee's progress under the Development Plan having at least the information specified on Appendix B to this Agreement, and shall be sent to the address on Appendix B.
- 1.4 "Investigator" means Dr. Roland (Doug) Shytle, Dr. Jun Tan, and Dr. Adam Smith while employed by Licensor.
- 1.5 "Know-How" means unpatented technology and/or information that was developed by the Investigator, including without limitation methods, processes, techniques, compounds, cell lines, materials, sequences, drawings, indications, data, results of tests, or studies, plans, and expertise, whether patentable or not, which relates specifically to the Licensed Patents and existing on the date hereof, only to the extent wholly owned and controlled by Licensor, except that, Know-How shall not include the Licensed Patents.
- 1.6 "Licensed Field" shall be limited to the use of LiSPro for the treatment of Alzheimer's Disease.

- 1.7 “Licensed Patents” means all of the following Licensor intellectual property:
- 1.7.1 the patent(s)/patent application(s) identified on Schedule 1 hereto;
  - 1.7.2 any and all United States and foreign patent applications claiming priority to any of the patent(s) and patent application(s) identified on Schedule 1 hereto (except that in the case of continuation-in-part application(s), only to the extent that the subject matter claimed in such continuation-in-part application(s) is supported under 35 U.S.C 112 in the patent(s)/patent application(s) identified on Schedule 1 hereto); and
  - 1.7.3 any and all patents issuing from the patent applications identified in section 1.6.1 and 1.6.2, including, but not limited to, letters patents, patents of addition, reissues, re-examinations, extensions, restorations, and supplementary protection certificates;
- all to the extent owned or controlled by Licensor.
- 1.8 “Licensed Product” and “Licensed Process” means:
- 1.8.1 In the case of a Licensed Product, any product or part thereof, on a country-by-country basis, that:
    - (a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which such product is made, used, imported or sold; or
    - (b) is manufactured by using a process that is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents, in any country in which any such process is used or in which any such product is used, imported, or sold; or
    - (c) incorporates, utilizes, or was developed utilizing, Know-How or that is manufactured using Know-How or using a process developed using Know-How.
  - 1.8.2 In the case of a Licensed Process, any process, on a country-by-country basis, that:
    - (a) is covered in whole or in part by an issued, unexpired claim or a pending claim contained in the Licensed Patents in any country in which such process is practiced; or
    - (b) incorporates, utilizes, or was developed utilizing, Know-How.
- 1.9 “Licensed Territory” shall be worldwide.
- 1.10 “Net Sales” means the total dollar amount invoiced on sales of Licensed Product and/or Licensed Processes by Licensee, Sublicensee or Affiliates. Total amount invoiced may include only promotional discounts allowed in amounts customary in the trade.
- 1.11 “Patent Challenge” means a challenge to the validity, patentability, enforceability and/or non-infringement of any of the Licensed Patents or otherwise opposing any of the Licensed Patents.
- 1.12 “Sublicense” means, directly or indirectly, to sublicense, grant any other right with respect to, or agree not to assert, any right licensed to Licensee under this Agreement.
- 1.13 “Sublicensee” means any third party to whom Licensee grants a Sublicense.

## **Section 2**      **Grant**

### 2.1      License.

#### 2.1.1      License Under Licensed Patents and Know-How

Subject to the terms of this Agreement, Licensors hereby grants to Licensee: a) a royalty-bearing, exclusive license, limited to the Licensed Field and the Licensed Territory, under the Licensed Patents to make, have made, develop, use, lease, import, export, offer to sell, sell and have sold Licensed Products and/or Licensed Processes, and b) a royalty bearing, non-exclusive license, limited to the Licensed Field and the Licensed Territory, under the Know-How to make, have made, develop, use, lease, import, export, offer to sell, sell and have sold Licensed Products and/or Licensed Processes. Licensors reserves to itself and to all nonprofit entities with which it collaborates the right under the Licensed Patents to make, have made, develop, import and use Licensed Products and Licensed Processes solely for their internal research, clinical and educational purposes. In addition, Licensors reserves to itself, as well as to all non-profit research institutions with which it collaborates, the right to use materials that might be covered under Licensed Patents solely for their internal research, educational, and clinical purposes and to meet all applicable governmental and peer review journal requirements governing the transfer of materials.

2.1.2      The license granted hereunder shall not be construed to confer any rights upon Licensee by implication, estoppel, or otherwise as to any technology not part of the Licensed Patents in the specified Licensed Field and specified Licensed Territory.

### 2.2      Sublicense.

2.2.1      Licensee may grant written Sublicenses under the Licensed Patents to third parties upon Licensors' approval, which approval shall not be unreasonably withheld. Any agreement granting a Sublicense shall state that the Sublicense is subject to the terms and conditions of this Agreement and to the termination of this Agreement. Licensee shall have the same responsibility for the activities of any Sublicensee or Affiliate as if the activities were directly those of Licensee.

2.2.2      Licensee shall provide Licensors with an unredacted copy of each Sublicense agreement and any agreement which transfers intellectual property rights granted hereunder, at least thirty (30) days prior to the execution of the Sublicense agreement.

2.2.3      In the event that Licensors notifies Licensee in writing of a third party's interest in a market or territory which Licensee is not addressing at the time of receipt of the notice, Licensee shall respond to Licensors in writing within thirty (30) days of receipt of such notice to inform Licensors whether Licensee intends to pursue the market or territory. If in such response, Licensee elects to forego the market or territory, Licensors may terminate in said market or territory the license granted in 2.1.1.

## **Section 3**      **Due Diligence**

### 3.1      Development.

3.1.1      Licensee agrees to and warrants that:

- (a) it has, or will obtain, the expertise necessary to independently evaluate the inventions of the Licensed Patents and Know-How; and
- (b) it will actively and diligently pursue the Development Plan, see Appendix A) to the end that the inventions of the Licensed Patents will be utilized to provide Licensed Products and/or Licensed Processes for sale in the retail market within the Licensed Field; and
- (c) it will diligently develop markets for Licensed Products and Licensed Processes;
- (d) and, until the date of first commercial sale of Licensed Products or Licensed Processes, it will supply Licensor with a written Development Report annually fifteen (15) days after the end of the calendar year (see Appendix B).

- 3.1.2 Licensee agrees that the first commercial sale of products to the retail customer shall occur on or before July 1, 2027 or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3 hereto. In addition, Licensee will meet the milestones shown in Appendix D or Licensor shall have the right to terminate this Agreement pursuant to Section 9.3. Licensee will notify Licensor in writing as each milestone is met.
- 3.1.3 Upon written request by Licensee to negotiate extensions of any milestones or due dates set forth in Appendix D, such request to be received by Licensor no less than ninety (90) days prior to any of the due dates subject of such request, set forth in this Section 3.1.3, such request fully describing Licensee's diligent efforts to achieve the milestone required to be met by such due date, Licensor shall consider in good faith such requests. Upon granting such request, Licensor and Licensee shall negotiate such extensions in good faith.
- 3.1.4 Licensor's policies may require approval of clinical trials involving technology invented by Licensor. Accordingly, Licensee will notify Licensor prior to commencing any clinical trials at the Licensor's facility or any affiliated medical facilities.
- 3.1.5 Every year Licensor is required to report on statistics that are relevant to growth of businesses in Florida. On January 31 and July 31 of each year, Licensee shall provide a report that includes: the current # of employees in Florida, the total # of employees, information about whether the company has gone public or been acquired, detail of the amount and sources of funding, any new products that have been introduced to the market, the number of employees who are USF graduates, and the number of USF interns for the period since the last report was received. This information will be held in confidence and provided in the aggregate. No confidential information will be identified with the specific company absent your agreement.

#### **Section 4      Payments**

##### **4.1      License Issue Fee.**

Licensee agrees to pay Licensor a License Issue Fee of Thirty Thousand Dollars (\$30,000.00) due on the Effective Date of this Agreement. The first Ten Thousand Dollars (\$10,000.00) is payable on or before July 31, 2018. The remaining Twenty Thousand Dollars (\$20,000.00) is due on or before October 31, 2018.

##### **4.2      Issuance of Equity.**

As further consideration for the rights granted to Licensee by this Agreement, as of the Effective Date, Licensee will issue to Licensor that number of shares of common stock of Licensee equal to one percent (1%) of the total number of issued and outstanding shares of Licensee on the Effective Date, according to the terms in Exhibit E, Equity Agreement.

- (a) If the company proposes to sell any equity securities or securities that are convertible into equity securities of the Company (collectively "Equity Securities") in a financing, then RESEARCH FOUNDATION and/or its Assignee (as defined below) will have the right to purchase up to that portion of the Equity Securities that equals the RESEARCH FOUNDATION'S then current, fully-diluted percentage ownership of the Company on the same terms and conditions as are offered with respect to such Equity Securities sold in such financing. The term "Assignee" means (a) any equity to which the RESEARCH FOUNDATION's preemptive rights have been assigned either by the RESEARCH FOUNDATION or another entity, or (b) any entity that is controlled by the University of South Florida or RESEARCH FOUNDATION; and
- (b) If the RESEARCH FOUNDATION and/or its Assignee has no current ownership of the Company, if the Company proposes to sell any Equity Securities, then RESEARCH FOUNDATION and/or its Assignee will have the right to purchase one percent (1%) of the securities issued in such offering on the same terms and conditions as are offered to the other purchasers in such financing.

#### 4.3 Royalty.

**Royalty on Licensed Patents.** In addition to the Section 4.1 License Issue Fee, Licensee agrees to pay to Licensor as earned royalties a royalty calculated as a percentage of Net Sales. The royalty is deemed earned as of the earlier of the date the Licensed Product and/or Licensed Process is actually sold and paid for, the date an invoice is sent by Licensee, it's Affiliate, or it's Sublicensee, or the date a Licensed Product and/or Licensed Process is transferred to a third party for any promotional reasons. Licensee shall pay to Licensor royalties as follows:

- (a) one and one-half percent (1.5%) for Net Sales of Licensed Products, for each product, on a country-by-country basis, as defined by Sections 1.7.1 (a), and 1.7.1(b); and
- (b) one and one-half percent (1.5%) for Net Sales of Licensed Processes, for each process, on a country-by-country basis, as defined by Section 1.7.2 (a); and
- (c) one and one-half percent (1.5%) for Net Sales of all other Licensed Products and Licensed Processes.

However, it is understood by both parties that there is an additional license in place between Licensee and Licensor labeled as "LIC18110" which includes a three percent (3%) royalty rate in the corresponding Section 4.3. At no time during which both this Agreement and LIC18110 are in force shall owed royalties exceed 4.5%. If LIC18110 should terminate due to patent term expiry while this Agreement remains in force, then the royalty for this Agreement shall become 3%.

#### 4.4 Other Payments.

4.4.1 Licensee agrees to pay Licensor minimum royalty payments, as follows:

Payment	Year
\$ 10,000.00	2023
\$ 15,000.00	2024
\$ 20,000.00	2025; and every year thereafter, for the life of this Agreement.

The minimum royalty shall be paid in advance on a quarterly basis for each year in which this Agreement is in effect. The first minimum royalty payment shall be due on December 31, 2022 and shall be in the amount of Two Thousand Five Hundred Dollars (\$2,500.00). The minimum royalty for a given year shall be due in advance and shall be paid in quarterly installments on March 31, June 30, September 30, and December 31 for the following quarter. Any minimum royalty paid in a calendar year will be credited against the earned royalties for that calendar year. It is understood that the minimum royalties will be applied to earned royalties on a calendar year basis, and that sales of Licensed Products and/or Licensed Processes requiring the payment of earned royalties made during a prior or subsequent calendar year shall have no effect on the annual minimum royalty due Licensor for other than the same calendar year in which the royalties were earned.

4.4.2 In addition to all other payments required under this Agreement, Licensee agrees to pay Licensor milestone payments, as follows:

Payment	Event
\$20,000.00	Upon First Pre-IND Meeting
\$15,000.00	Upon IND filing
\$40,000.00	Upon first dosing of a patient in a clinical trial
\$100,000.00	Upon Completion of First Phase Clinical Trial
\$250,000.00	Upon first patient treated in a Phase III Clinical Trial
\$2,000,000.00	Upon FDA Approval

Sublicenses. In respect to Sublicenses granted by Licensee under 2.2.1 above, Licensee shall pay to Licensor an amount equal to what Licensee would have been required to pay to Licensor had Licensee sold the amount of Licensed Product or Licensed Process sold by such Sublicensee. In addition, if Licensee receives any fees, minimum royalties, milestone payments, or other payments arising from the Sublicense, and such payments are not earned royalties as defined in Section 4.3 above, then Licensee shall pay Licensor fifty percent (50%) of such payments within thirty (30) days of receipt thereof. Such payments shall not be allocated, off-set or otherwise reduced as a result of including rights other than those licensed hereunder in such permitted written Sublicense. Licensee shall not receive from Sublicensees anything of value in lieu of cash payments in consideration arising from any Sublicense under this Agreement without the express prior written permission of Licensor.

4.5 Accounting for Payments.

4.5.1 Amounts owing to Licensor under Section 4.3 shall be paid on a quarterly basis after the amount of minimum royalties paid is exceeded, with such amounts due and received by Licensor on or before the thirtieth day following the end of the calendar quarter ending on March 31, June 30, September 30 or December 31 in which such amounts were earned. All royalties owing with respect to Net Sales stated in currencies other than U.S. dollars shall be converted at the rate shown in the Federal Reserve Noon Valuation - Value of Foreign Currencies on the day preceding the payment due date.

- 4.5.2 Any amounts which remain unpaid after the date they are due to Licensor shall accrue interest from the due date at the rate of 1.5% per month. However, in no event shall this interest provision be construed as a grant of permission for any payment delays. Licensee shall also be responsible for repayment to Licensor of any attorney, collection agency, or other out-of-pocket Licensor expenses required to collect overdue payments due under this Section 4 or any other applicable Section of this Agreement.
- 4.5.3 Except as otherwise directed, all amounts owing to Licensor under this Agreement shall be paid in U.S. dollars to Licensor at the following address:
- USF Research Foundation  
Attn: Business Manager  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612
- 4.5.4 A certified full accounting statement showing how any amounts payable to Licensor under Section 4 have been calculated shall be submitted to Licensor on the date of each such payment. In addition to being certified, such accounting statements shall contain a written representation signed by an executive officer of Licensee that states that the statements are true, accurate, and fairly represent all amounts payable to Licensor pursuant to this Agreement. For earned royalties, such accounting shall be on a per-country and product line, model or trade name basis and shall be summarized on the form shown in Appendix C – Licensor Royalty Report of this Agreement. For earned royalties, in the event no payment is owed to Licensor because the amount of minimum royalties paid has not been exceeded or otherwise, an accounting demonstrating that fact shall be supplied to Licensor.
- 4.5.5 Licensor is exempt from paying income taxes under U.S. law. Therefore, all payments due under this Agreement shall be made without deduction for taxes, assessments, or other charges of any kind which may be imposed on Licensor by any government outside of the United States or any political subdivision of such government with respect to any amounts payable to Licensor pursuant to this Agreement. All such taxes, assessments, or other charges shall be assumed by Licensee.

## **Section 5**

### **Certain Warranties and Disclaimers of Licensor**

- 5.1 Licensor warrants that, except as otherwise provided under Section 17.1 of this Agreement with respect to U.S. Government interests, it is the owner or exclusive licensee of the Licensed Patents or otherwise has the right to grant the licenses granted to Licensee in this Agreement. However, nothing in this Agreement shall be construed as:
- (a) a warranty or representation by Licensor as to the validity or scope of any right included in the Licensed Patents; or
  - (b) a warranty or representation that anything made, used, sold or otherwise disposed of under the license granted in this Agreement will or will not infringe patents of third parties; or
  - (c) an obligation to bring or prosecute actions or suits against third parties for infringement of Licensed Patents; or
  - (d) an obligation to furnish any services other than those specified in this Agreement; or

- (e) a warranty or representation by Licensor that it will not grant licenses to others to make, use or sell products not covered by the claims of the Licensed Patents which may be similar and/or compete with products made or sold by Licensee.

5.2 EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, LICENSOR MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENT RIGHTS CLAIMS, ISSUED OR PENDING. LICENSOR ASSUMES NO RESPONSIBILITIES WHATSOEVER WITH RESPECT TO USE, SALE, OR OTHER DISPOSITION BY LICENSEE, ITS SUBLICENSEE(S), OR THEIR VENDEES OR OTHER TRANSFEREES OF PRODUCT INCORPORATING OR MADE BY USE OF INVENTIONS LICENSED UNDER THIS AGREEMENT.

#### **Section 6**      **Record Keeping**

- 6.1 Licensee and its Sublicensee(s) shall keep books and records sufficient to verify the accuracy and completeness of Licensee's and its Sublicensee(s)'s accounting referred to above, including without limitation, inventory, purchase and invoice records, manufacturing records, sales analysis, general ledgers, financial statements, and tax returns relating to the Licensed Products and/or Licensed Processes. Such books and records shall be preserved for a period not less than six years after they are created or as required by federal law, both during and after the term of this Agreement.
- 6.2 Licensee and its Sublicensee(s) shall take all steps necessary so that Licensor may, within thirty (30) days of its written request, audit, review and/or copy all of the books and records at a single U.S. location to verify the accuracy of Licensee's and its Sublicensee(s)'s accounting. Such review may be performed by any authorized employees of Licensor as well as by any attorneys and/or accountants designated by Licensor, upon reasonable notice and during regular business hours. If a deficiency with regard to any payment hereunder is determined, Licensee and its Sublicensee(s) shall pay the deficiency within thirty (30) days of receiving notice thereof along with applicable interest as described in Section 4.5.12. If a royalty payment deficiency for a calendar year exceeds three percent (3%) of the royalties paid for that year, then Licensee and its Sublicensee(s) shall be responsible for paying Licensor's out-of-pocket expenses incurred with respect to such review.
- 6.3 At any time during the term of this Agreement, Licensor may request in writing that Licensee verify the calculation of any past payments owed to Licensor through the means of a self-audit. Within ninety (90) days of the request, Licensee shall complete a self-audit of its books and records to verify the accuracy and completeness of the payments owed. Within thirty (30) days of the completion of the self-audit, Licensee shall submit to Licensor a report detailing the findings of the self-audit and the manner in which it was conducted in order to verify the accuracy and completeness of the payments owed. If Licensee has determined through its self-audit that there is any payment deficiency, Licensee shall pay Licensor the deficiency along with applicable interest under Section 4.5.1 with the submission of the self-audit report to Licensor.

#### **Section 7**      **Patent Prosecution**

- 7.1 Licensor shall prosecute and maintain the Licensed Patents using counsel of its choice. Licensor shall provide Licensee with copies of all documents sent to and received from the United States Patent and Trademark Office and foreign patent offices relating to Licensed Patents. Licensee agrees to keep such information confidential.



- 7.2 Licensee shall pay to Licensor the sum of Twelve Thousand Two Hundred Twenty-Five Dollars (\$12,225.00), to reimburse any and all expenses associated with preparation, filing, prosecution, issuance, maintenance, defense, and reporting of the Licensed Patents incurred prior to the Effective Date within thirty (30) days of the Effective Date. (**NOTE:** the above referenced dollar amount in this Section 7.2 is subject to change, as all related patent prosecution expense invoices may not have been received from the law firm at the time of license terms negotiation.)
- 7.3 Licensee shall be responsible for and pay all costs and expenses incurred by Licensor related to the preparation, filing, prosecution (including interferences), issuance, maintenance, defense (including oppositions) and reporting of the Licensed Patents subsequent to and separate of those expenses cited in Section 7.2 within thirty (30) days of receipt of an invoice from Licensor. It shall be the responsibility of Licensee to keep Licensor fully apprised of the "small entity" status of Licensee and all Sublicensees with respect to the U.S. patent laws and with respect to the patent laws of any other countries, if applicable, and to inform Licensor of any changes in writing of such status, within thirty (30) days of any such change. In the event that additional licenses are granted to licensees for alternate fields-of-use, patent expenses associated with Licensed Patents will be divided proportionally between the number of existing licensees. In the case of foreign patent protection, if Licensee gives sixty (60) days' notice that it intends to decline to reimburse Licensor for patent expenses for any Licensed Patent in any particular country, then the license granted hereunder respecting such Licensed Patent shall terminate after such sixty (60) days and Licensee relinquishes the right to commercialize Licensed Products in the specified country.

## **Section 8      Infringement and Invalidity**

- 8.1 Licensee shall inform Licensor promptly in writing of any alleged infringement of the Licensed Patents by a third party and of any available evidence thereof.
- 8.2 During the term of this Agreement, Licensor shall have the right, but shall not be obligated, to prosecute at its own expense any such infringements of the Licensed Patents. If Licensor prosecutes any such infringement, Licensee agrees that Licensor may include Licensee as a co-plaintiff in any such suit, without expense to Licensee.
- 8.3 If within six (6) months after having been notified of any alleged infringement, Licensor shall have been unsuccessful in persuading the alleged infringer to desist and shall not have brought an infringement action against the alleged infringer, or if Licensor shall notify Licensee at any time prior thereto of its intention not to bring suit against the alleged infringer, then, and in those events only, Licensee shall have the right, but shall not be obligated, to prosecute at its own expense any infringement of the Licensed Patents, and Licensee may, for such purposes, use the name of Licensor as party plaintiff. No settlement, consent judgment or other voluntary final disposition of the suit may be entered into without the consent of Licensor, which consent shall not be unreasonably withheld. Licensee shall indemnify Licensor against any order for costs that may be made against Licensor in such proceedings.
- 8.4 In the event that a declaratory judgment action is brought against Licensor or Licensee by a third party alleging invalidity, unpatentability, unenforceability, or non-infringement of the Licensed Patents, Licensor, at its option, shall have the right within twenty (20) days after commencement of such action to take over the sole defense of the action at its own expense. If Licensor does not exercise this right, Licensee shall be responsible for the sole defense of the action at Licensee's sole expense, subject to Sections 8.5 and 8.6.

- 8.5 In the event that Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, Licensor shall have the right, but not the obligation, to voluntarily join such litigation, represented by its own counsel at its own expense. In the event that Licensor or Licensee shall undertake the enforcement by litigation and/or defense of the Licensed Patents by litigation, any recovery of damages by Licensor or Licensee for any such suit shall be applied first in satisfaction of any unreimbursed expenses and legal fees of Licensor relating to the suit, and next toward reimbursement of any unreimbursed expenses and legal fees of Licensee relating to the suit. The balance remaining from any such recovery shall be divided equally between Licensee and Licensor.
- 8.6 In any suit in which either party is involved to enforce or defend the Licensed Patents pursuant to this Agreement, the other party hereto shall, at the request and expense of the party initiating such suit, cooperate in all respects and, to the extent possible, have its employees testify, if requested, and make available relevant records, papers, information, samples, specimens, and the like.
- 8.7 In the event Licensee contests the validity of any Licensed Patents, unless and until Licensor terminates this Agreement pursuant to 9.3.10, Licensee shall continue to pay royalties and make other payments pursuant to this Agreement with respect to the contested Licensed Patent(s) as if such contest were not underway until the contested Licensed Patent(s) is adjudicated invalid or unenforceable by a court of last resort.

## **Section 9**

### **Term and Termination**

- 9.1 The term of this license shall begin on the Effective Date of this Agreement and continue until the later of the date that no Licensed Patent remains a pending application or an enforceable patent, the end date of any period of market exclusivity granted by a governmental regulatory body, on a country by country basis, or the date on which Licensee's obligation to pay royalties expires pursuant to Section 4.3 above.
- 9.2 Licensee may terminate this Agreement at any time by giving at least sixty (60) days written notice of such termination to Licensor. Such a notice shall be accompanied by a statement of the reasons for termination.
- 9.3 Licensor may terminate this Agreement if (a) Licensee (i) is delinquent on any report or payment; (ii) is not diligently developing and commercializing Licensed Products and Licensed Processes; (iii) misses a milestone described in Appendix D; (iv) is in breach of any provision; (v) provides any false report; (vi) goes into bankruptcy, liquidation or proposes having a receiver control any assets; (vii) violates any laws or regulations of applicable government entities; or (viii) shall cease to carry on its business pertaining to Licensed Patents; or (b) if payments of earned royalties under Section 4.3, once begun, cease for more than two (2) calendar quarters. Termination under this Section 9.3 will take effect 30 days after written notice by Licensor, unless Licensee remedies the problem in that 30-day period, except that termination under Section 9.3 (vi) will occur immediately and automatically upon the occurrence of the event and require no action by Licensor.
- 9.4 If Licensee or any of its Affiliates brings a Patent Challenge against Licensor or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may immediately terminate this Agreement and/or the license granted hereunder. If a Sublicensee brings a Patent Challenge against Licensor, or assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), then Licensor may send a written demand to Licensee to terminate such Sublicense. If Licensee fails to so terminate such Sublicense within forty-five (45) days after Licensor's demand, Licensor may immediately terminate this Agreement and/or the license granted hereunder.

- 9.5 If Licensee, any of its Affiliates or a Sublicensee (i) brings a Patent Challenge against Licensor or (ii) assists another party in bringing a Patent Challenge against Licensor (except as required under a court order or subpoena), and if Licensor does not choose to exercise its rights to terminate this Agreement pursuant to Section 9.4 then, in the event that such the Patent Challenge is successful, Licensee will have no right to recoup any consideration, including royalties, paid during the period of challenge. In the event that the Patent Challenge is unsuccessful, Licensee shall reimburse Licensor for all reasonable legal fees and expenses incurred in its defense against the Patent Challenge.
- 9.6 Licensor may immediately terminate this Agreement upon the occurrence of the second separate default by Licensee within any consecutive three-year period for failure to pay royalties, patent or any other expenses when due.
- 9.7 Upon the termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination. Licensee shall remain obligated to provide an accounting for and to pay royalties earned to the date of termination, and any minimum royalties shall be prorated as of the date of termination by the number of days elapsed in the applicable calendar year. Licensee may, however, after the effective date of such termination, sell all Licensed Products, and complete Licensed Products in the process of manufacture at the time of such termination and sell the same, provided that Licensee shall remain obligated to provide an accounting for and to pay running royalties thereon.
- 9.8 Licensee shall be obligated to deliver to Licensor, within ninety days of the date of termination of this agreement, complete and unredacted copies of all documentation prepared for or submitted for all regulatory approvals of Licensed Products or Licensed Processes.

#### **Section 10**     **Assignability**

This Agreement may not be transferred or assigned by Licensee except with the prior written consent of Licensor, in which case assignee assumes all responsibilities under this license.

#### **Section 11**     **Dispute Resolution Procedures**

##### **11.1**     Mandatory Procedures.

In the event either party intends to file a lawsuit against the other with respect to any matter in connection with this Agreement, compliance with the procedures set forth in this Section shall be a condition precedent to the filing of such lawsuit, other than for injunctive relief. Either party may terminate this Agreement as provided in this Agreement without following the procedures set forth in this section.

11.1.1     When a party intends to invoke the procedures set forth in this section, written notice shall be provided to the other party. Within thirty (30) days of the date of such notice, the parties agree that representatives designated by the parties shall meet at mutually agreeable times and engage in good faith negotiations at a mutually convenient location to resolve such dispute.

11.1.2     If the parties fail to meet within the time period set forth in section 11.1.1 above or if either party subsequently determines that negotiations between the representatives of the parties are at an impasse, the party declaring that the negotiations are at an impasse shall give notice to the other party stating with particularity the issues that remain in dispute.

- 11.1.3 Not more than 15 days after the giving of such notice of issues, each party shall deliver to the other party a list of the names and addresses of at least three individuals, any one of whom would be acceptable as a neutral advisor in the dispute (the "Neutral Advisor") to the party delivering the list. Any individual proposed as a Neutral Advisor shall have experience in determining, mediating, evaluating, or trying intellectual property litigation and shall not be affiliated with the party that is proposing such individual.
- 11.1.4 Within 10 days after delivery of such lists, the parties shall agree on a Neutral Advisor. If they are unable to agree within that time, within 5 days, they shall each select one individual from the lists. Within 5 days, the individuals so selected shall meet and appoint a third individual from the lists to serve as the Neutral Advisor. Within 30 days after the selection of a Neutral Advisor:
- (a) The parties shall each provide a written statement of the issues in dispute to the Neutral Advisor; and
  - (b) The parties shall meet with the Neutral Advisor in Tampa, Florida on a date and time established by the Neutral Advisor. The meeting must be attended by persons authorized to make final decisions on behalf of each party with respect to the dispute. At the meeting, each party shall make a presentation with respect to its position concerning the dispute. The Neutral Advisor will then discuss the issues separately with each party and attempt to resolve all issues in the dispute. At the meeting, the parties will enter into a written settlement agreement with respect to all issues that are resolved. Such settlement agreement shall be final and binding with respect to such resolved issues and may not be the subject of any lawsuit between the parties, other than a suit for enforcement of the settlement agreement.
- 11.1.5 The expenses of the neutral advisor shall be shared by the parties equally. All other out-of-pocket costs and expenses for the alternative dispute resolution procedure required under this Section shall be paid by the party incurring the same.
- 11.1.6 Positions taken and statements made during this alternative dispute resolution procedure shall be deemed settlement negotiations and shall not be admissible for any purpose in any subsequent proceeding.

11.2 Failure to Resolve Dispute.

If any issue is not resolved at the meeting with the Neutral Advisor, either party may file appropriate administrative or judicial proceedings with respect to the issue that remains in dispute. No new issues may be included in the lawsuit without the mandatory procedures set forth in this section having first been followed.

**Section 12 Product Liability; Conduct of Business**

- 12.1 Licensee and its Sublicensee(s) shall, at all times during the term of this Agreement and thereafter, indemnify, defend and hold Licensor, its board, University and its Affiliates and Trustees, the Florida Board of Governors, and each of their directors, officers, employees, and agents, and the inventors of the Licensed Patents, regardless of whether such inventors are employed by Licensor at the time of the claim, harmless against all claims and expenses, including legal expenses and reasonable attorneys' fees, whether arising from a third party claim or resulting from Licensor's enforcing this indemnification clause against Licensee, arising out of the death of or injury to any person or persons or out of any damage to property and against any other claim, proceeding, demand, expense and liability of any kind whatsoever (other than patent infringement claims) resulting from the development, production, manufacture, sale, use, lease, consumption, marketing, or advertisement of Licensed Products or Licensed Process(es) or arising from any right or obligation of Licensee hereunder. Notwithstanding the above, Licensor at all times reserves the right to retain counsel of its own to defend Licensor's, its board, University and its Affiliates' and Trustees, the Florida Board of Governors', and the inventor's interests.

- 12.2 Licensee warrants that it now maintains and will continue to maintain liability insurance coverage appropriate to the risk involved in development, producing, manufacturing, clinical trials, selling, marketing, using, leasing, consuming, or advertising the products subject to this Agreement and that such insurance coverage lists Licensor, its Affiliates, its Trustees, the Florida Board of Governors, and the inventors of the Licensed Patents as additional insureds. Within ninety (90) days after the execution of this Agreement and thereafter annually between January 1 and January 31 of each year, Licensee will present evidence to Licensor that the coverage is being maintained with Licensor, University and its Affiliates and Trustees, the Florida Board of Governors, and its inventors listed as additional insureds. In addition, Licensee shall provide Licensor with at least thirty (30) days prior written notice of any change in or cancellation of the insurance coverage.

**Section 13** **Use of Names**

Licensee and its Sublicensee(s) shall not use the names of Licensor, nor of any of either institution's employees, agents, or affiliates, nor the name of any inventor of Licensed Patents, nor any adaptation of such names, in any promotional, advertising or marketing materials or any other similar form of publicity, or to suggest any endorsement by the such entities or individuals, without the prior written approval of Licensor in each case.

**Section 14** **Miscellaneous**

- 14.1 This Agreement shall be construed in accordance with the internal laws of the State of Florida.
- 14.2 The parties hereto are independent contractors and not joint venturers or partners.
- 14.3 Licensee shall ensure that it applies patent markings that meet all requirements of U.S. law, 35 U.S.C. §287, with respect to all Licensed Products subject to this Agreement.
- 14.4 This Agreement constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, shall vary or modify the written terms of this Agreement. Neither party shall claim any amendment, modification, or release from any provisions of this Agreement by mutual agreement, acknowledgment, or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Agreement.
- 14.5 Licensee shall not encumber or otherwise grant a security interest in any of the rights granted hereunder to any third party.
- 14.6 Licensee acknowledges that it is subject to and agrees to abide by the United States laws and regulations (including the Export Administration Act of 1979 and Arms Export Control Act) controlling the export of technical data, computer software, laboratory prototypes, biological material, and other commodities. The transfer of such items may require a license from the cognizant agency of the U.S. Government or written assurances by Licensee that it shall not export such items to certain foreign countries without prior approval of such agency. Licensor neither represents that a license is or is not required or that, if required, it shall be issued.

14.7 Licensee is responsible for any and all wire/bank fees associated with all payments due to Licensor pursuant to this agreement.

14.8 Survival.

The provisions of this Section shall survive termination of this Agreement. Upon termination of the Agreement for any reason, the following sections of the License Agreement will remain in force as non-cancelable obligations:

- Section 6 Record Keeping
- Section 9 Requirement to pay royalties on sale of Licensed Products made, and in process, at time of License Agreement termination
- Section 12 Product Liability; Conduct of Business
- Section 13 Use of Names
- Section 18 Confidentiality

## **Section 15**   **Notices**

Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given (a) when delivered personally; or (b) if sent by facsimile transmission, when receipt thereof is acknowledged at the facsimile number of the recipient as set forth below; or (c) the second day following the day on which the notice has been delivered prepaid to a national air courier service; or (d) five (5) business days following deposit in the U.S. mail if sent certified mail, (return receipt acknowledgement is not required to certify delivery).

15.1 All payments and royalty reports to:

USF Research Foundation  
Attn: Business Manager  
3802 Spectrum Blvd, Suite 100  
Tampa, FL 33612

Development reports; updates; equity agreements, proxy statements and shareholder information; and all other notices and communications to:

USF Technology Transfer Office/Patents & Licensing  
Attn: Associate Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, FL 33612

15.2 If to Licensee:

Alzamend Neuro, Inc.  
Attn: CEO  
50 W Broadway, Suite #300  
Salt Lake City, UT 84101

## **Section 16**   **Contract Formation and Authority**

The submission of this Agreement does not constitute an offer, and this document shall become effective and binding only upon the execution by duly authorized representatives of both Licensee and Licensor. Copies of this Agreement that have not been executed and delivered by both Licensor and Licensee shall not serve as a memorandum or other writing evidencing an agreement between the parties. This Agreement shall automatically terminate and be of no further force and effect, without the requirement of any notice from Licensor to Licensee, if Licensor does not receive the License Issue Fee or certificates representing shares issued to Licensor pursuant to this Agreement, as applicable, within thirty (30) days of the Effective Date.

- 16.1 Licensor and Licensee hereby warrant and represent that the persons signing this Agreement have authority to execute this Agreement on behalf of the party for whom they have signed.
- 16.2 Force Majeure.

No default, delay, or failure to perform on the part of Licensee or Licensor shall be considered a default, delay or failure to perform otherwise chargeable hereunder, if such default, delay or failure to perform is due to causes beyond either party's reasonable control including, but not limited to: strikes, lockouts, or inactions of governmental authorities, epidemics, war, embargoes, fire, earthquake, hurricane, flood, acts of God, or default of common carrier. In the event of such default, delay or failure to perform, any date or times by which either party is otherwise scheduled to perform shall be extended automatically for a period of time equal in duration to the time lost by reason of the excused default, delay or failure to perform.

#### **Section 17**      **United States Government Interests**

- 17.1 It is understood that the United States Government (through any of its agencies or otherwise) has funded research during the course of or under which any of the inventions of the Licensed Patents were conceived or made. The United States Government is entitled, as a right, under the provisions of 35 U.S.C. §202-212 and applicable regulations of Title 37 of the Code of Federal Regulations, to a non-exclusive, nontransferable, irrevocable, paid-up license to practice or have practiced the inventions of such Licensed Patents for governmental purposes. Any license granted to Licensee in this Agreement shall be subject to such right.
- 17.2 Licensee agrees that for Licensed Products covered by the Licensed Patents that are subject to the non-exclusive royalty-free license to the United States Government, said Licensed Products will be manufactured substantially in the United States. Licensee further agrees that it shall abide by all the requirements and limitations of U.S. Code, Title 35, Chapter 18, and implementing regulations thereof, for all patent applications and patents invented in whole or in part with federal money.

#### **Section 18**      **Confidentiality**

Each Party shall maintain all information of the other Party which is treated by such other Party as proprietary or confidential (referred to herein as "Confidential Information") in confidence, and shall not disclose, divulge or otherwise communicate such confidential information to others, or use it for any purpose, except pursuant to, and in order to carry out, the terms and objectives of this Agreement, and each party hereby agrees to exercise every reasonable precaution to prevent and restrain the unauthorized disclosure of such confidential information by any of its Affiliates, directors, officers, employees, consultants, subcontractors, Sublicensees or agents. The parties agree to keep the terms of this Agreement confidential, provided that each party may disclose this Agreement to their authorized agents and investors who are bound by similar confidentiality provisions. Notwithstanding the foregoing, Confidential Information of a party shall not include information which: (a) was lawfully known by the receiving party prior to disclosure of such information by the disclosing party to the receiving party; (b) was or becomes generally available in the public domain, without the fault of the receiving party; (c) is subsequently disclosed to the receiving party by a third party having a lawful right to make such disclosure; (d) is required by law, rule, regulation or legal process to be disclosed, provided that the receiving party making such disclosure shall take all reasonable steps to restrict and maintain to the extent possible confidentiality of such disclosure and shall provide reasonable notice to the other party to allow such party the opportunity to oppose the required disclosure; or (e) has been independently developed by employees or others on behalf of the receiving party without access to or use of disclosing party's information as demonstrated by written record. Each party's obligations under this Section 18 shall extend for a period of five (5) years from termination or expiration of this Agreement.

**Section 19      University Rules and Regulations**

Licensee understands and agrees that Licensor's personnel who are engaged by Licensee, whether as consultants, employees or otherwise, or who possess a material financial interest in Licensee, are subject to Florida's rule regarding outside activities and financial interests set forth in Florida Administrative Code Rule 6C1-1.011, the Licensor's Intellectual Property Policy, and a monitoring plan which addresses conflicts of interests associated therewith. Any term or condition of an agreement between Licensee and such personnel which seeks to vary or override such personnel's obligations to Licensor may not be enforced against such personnel or the Licensor, without the express written consent of an individual authorized to vary or waive such obligations on behalf of the Licensor. Furthermore, should an interest of Licensee conflict with the interest of the Licensor, Licensor's personnel are obligated to resolve such conflicts according to the guidelines and policies set forth by the Licensor.

*Signature Page Follows*



IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement on the dates indicated below.

UNIVERSITY OF SOUTH FLORIDA RESEARCH FOUNDATION, INC.

\_\_\_\_\_ Date: \_\_\_\_\_, 2018

Valerie Landrio McDevitt, Associate Vice President  
Technology Transfer Office

ALZAMEND NEURO, INC.

\_\_\_\_\_ Date: July 18, 2018

Philip E. Mansour, President and CEO

ACKNOWLEDGED AND AGREED:

UNIVERSITY OF SOUTH FLORIDA BOARD OF  
TRUSTEES A PUBLIC BODY CORPORATE

INVENTOR

\_\_\_\_\_

Keith Anderson, Director

\_\_\_\_\_

Dr. Roland (Doug) Shytle

INVENTOR

\_\_\_\_\_

Dr. Jun Tan

**Schedule I**

United States Patent No. 9,603,869, entitled "Lithium Co-Crystals for Treatment of Neuropsychiatric Disorders", filed 05/21/2016 and granted 03/28/2017.

## Appendix A - Development Plan

### I. Development Program

#### A. Development activities to be undertaken

1. Continue with Reg A+ funding strategy already in place.
2. By October 1, 2018, contract with a clinical research organization (CRO) to prepare IND package and plan first trial.
3. By January 1, 2019 identify and contract the GMP manufacturer for clinical grade LiSPro.

#### B. Estimated total development time – Achieve FDA approval by July 1, 2026

### II. Governmental Approval – FDA timeline

Due Date	Event
November 1, 2019	Pre-IND Meeting
6 months from Pre-IND Meeting	IND filing
12 months from IND filing	First dosing of a patient in a clinical trial
12 months from completion of the first dosing of a patient	Completion of first clinical trial
12 months from completion of the first Phase II Clinical Trial	First patient treated in a Phase III Clinical Trial
8 years from the Effective Date of this Agreement	FDA Approval

### III. Anticipated date of product launch – July 1, 2027

## **Appendix B - Development Report**

When appropriate, indicate estimated start date and finish date for activities.

- I. Date Development Plan Initiated and Time Period Covered by this Report.
- II. Development Report (4-8 paragraphs).
  - A. Activities completed since last report including the object and parameters of the development, when initiated, when completed and the results.
  - B. Activities currently under investigation, i.e., ongoing activities including object and parameters of such activities, when initiated, and projected date of completion.
- III. Future Development Activities (4-8 paragraphs).
  - A. Activities to be undertaken before next report including, but not limited to, the type and object of any studies conducted and their projected starting and completion dates.
  - B. Estimated total development time remaining before a product will be commercialized.
- IV. Changes to Initial Development Plan (2-4 paragraphs).
  - A. Reasons for change.
  - B. Variables that may cause additional changes.
- V. Items to be Provided if Applicable:
  - A. Information relating to Licensed Products or Licensed Processes that has become publicly available, e.g., published articles, competing products, patents, etc.
  - B. Development work being performed by third parties, other than Licensee, to include name of third party, reasons for use of third party, planned future uses of third parties including reasons why and type of work.
  - C. Update of competitive information trends in industry, government compliance (if applicable) and market plan.
  - D. Information and copies of relevant materials evidencing the status of any patent applications or other protection relating to Licensed Products, or Licensed Processes or the Licensed Patents.

### **PLEASE SEND DEVELOPMENT REPORTS TO:**

USF Division of Patents & Licensing  
Attn: Associate Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612

**Appendix C - Licensor Royalty Report**

**Licensee:** \_\_\_\_\_  
**Agreement No.:** \_\_\_\_\_  
**Inventor:** \_\_\_\_\_  
**Technology#:** \_\_\_\_\_  
**Period Covered:** \_\_\_\_\_ From:    /    / 2 \_\_\_\_\_ Through:    /    / 2 \_\_\_\_\_  
**Prepared By:** \_\_\_\_\_  
**Date:** \_\_\_\_\_  
**Approved By:** \_\_\_\_\_  
**Date:** \_\_\_\_\_

If license covers several major product lines, please prepare a separate report for each line. Then combine all product lines into a summary report.

**Report Type:** ☐ **Single Product Line Report:** \_\_\_\_\_  
                  ☐ **Multiproduct Summary Report.** Page 1 of \_\_\_\_\_ Pages  
                  ☐ **Product Line Detail.** Line: \_\_\_\_\_ Tradename: \_\_\_\_\_ Page: \_\_\_\_\_  
**Report Currency:** ☐ **U. S. Dollars**      ☐ **Other** \_\_\_\_\_

	Unit	Gross	* Less:	Net	Royalty	Period Royalty Amount	
Country	Sales	\$\$ Sales	Allowances	\$\$ Sales	Rate	This Year	Last Year
U.S.A.							
Canada							
Europe:							
Japan							
Other:							
<b>TOTAL:</b>							

Total Royalty: \_\_\_\_\_ Conversion Rate: \_\_\_\_\_ Royalty in U.S. Dollars: \$ \_\_\_\_\_

The following royalty forecast is non-binding and for Licensor's internal planning purposes only:

Royalty Forecast Under This Agreement:

Next Quarter: \_\_\_\_\_ Q2: \_\_\_\_\_ Q3: \_\_\_\_\_ Q4: \_\_\_\_\_

\* On a separate page, please indicate the reasons for returns or other adjustments if significant.  
Also note any unusual occurrences that affected royalty amounts during this period.  
To assist Licensor's forecasting, please comment on any significant expected trends in sales volume.

**PLEASE SEND ROYALTY REPORTS TO:**

USF Research Foundation  
Attn: Business Manager  
3802 Spectrum Blvd, Suite 100  
Tampa, Florida 33612

#### **Appendix D - Milestones**

1. Licensee has already provided Licensor a preliminary business plan. By January 1, 2019, Licensee will provide Licensor a detailed document covering Licensee's plans as to projected product development, and financial forecasts through the initiation of the Phase III Clinical Trial ("Business Plan"). Licensor will treat this Business Plan as Confidential Information and to protect it as Licensor would its own Confidential Information.
2. By 12 months from the Effective Date, Licensee will have Five Million Dollars (\$5,000,000) of available non-contingent, operating capital to proceed with the exploration and development of Licensed Product. Capital will be from a third party who may or may not be an investor in Licensee and unused capital will be on deposit in a financial institution acceptable to both Licensor and Licensee.
3. Company will meet the following Regulatory Milestones:

<b>Due Date</b>	<b>Event</b>
November 1, 2019	Pre-IND Meeting
6 months from Pre-IND Meeting	IND filing
12 months from IND filing	First dosing of a patient in a clinical trial
12 months from completion of the first dosing of a patient	Completion of first clinical trial
12 months from completion of the first Phase II Clinical Trial	First patient treated in a Phase III Clinical Trial
8 years from the Effective Date of this Agreement	FDA Approval

By July 1, 2027, Licensee will have a first sale of Licensed Product.

## **Appendix E - Equity Agreement - USFRF equity**

THIS EQUITY AGREEMENT (the "Equity Agreement") is made effective July 02, 2018 by and between The University of South Florida Research Foundation, Inc. (hereinafter called "Licensor"), a non-stock, nonprofit Florida corporation under Chapter 617 Florida Statutes, and a direct support organization of the University of South Florida ("University") pursuant to section 1004.28 Florida Statutes, and Alzamend Neuro, Inc. (hereinafter called "Licensee"), a corporation organized and existing under the laws of Delaware.

WHEREAS, Licensor and Licensee have entered into a certain License Agreement with respect to certain inventions owned by Licensor or in which Licensor has a joint, undivided interest;

WHEREAS, as an accommodation to Licensee, Licensor is willing to accept shares of common stock of Licensee (the "Shares") in lieu of charging Licensee certain fees under the License Agreements.

NOW THEREFORE, in consideration of the mutual covenants and agreements set forth below, the parties covenant and agree as follows:

### **Section 1      Definitions**

For the purpose of this Agreement, the Exhibit A definitions shall apply. Capitalized terms used and not otherwise defined herein shall have the meanings assigned thereto in the License Agreements.

### **Section 2      Issuance of Shares to USFRF; Closing Deliveries**

#### **2.1      Issuance of Shares**

- 2.1.1 As further consideration for the rights granted to Licensee by this Agreement, as of the Effective Date, (i) Licensee will issue to USFRF that number of shares of common stock of Licensee equal to one percent (1%) of the total number of issued and outstanding shares of Licensee on the Effective Date. If at any time after the Effective Date of this Agreement and before Licensee receives a total of Five Million Dollars (\$5,000,000.00) cash in exchange for the issuance of (i) Licensee's equity securities and/or (ii) debt securities that are convertible into or exercisable or exchangeable for Licensee's equity securities, Licensee issues any (a) shares of common stock or (b) securities that are convertible into or exercisable or exchangeable for shares of Licensee's common stock, then in such event, Licensee shall issue additional shares of common stock to USFRF such that immediately after such issuance to USFRF the total number of shares issued to USFRF under this Section constitutes one percent (1%) of the total number of issued and outstanding shares of Licensee calculated on a fully diluted basis. Licensee shall deliver, or cause to be delivered, to USFRF a stock certificate, duly signed by appropriate officers of Licensee and issued in USFRF's name, representing all of the Shares required to be issued to USFRF.
- 2.1.2 All Shares shall be fully-paid and non-assessable upon their issuance to USFRF. USFRF's execution of this Agreement and the License Agreements shall be deemed full consideration for the issuance of the Shares, and no additional consideration for such Shares shall be due from USFRF. No Shares shall be subject to any restrictions on their transfer other than the restrictions specified in Exhibit C hereto.



- 2.1.3 If USFRF owns 8% or less of the outstanding shares of common stock of Licensee, or will own 8% or less as a result of an initial public offering by Licensee, USFRF's shares will not be subject to any lock-up requirement or other restriction on selling such shares, other than as required by law, in connection with the initial public offering or any public offering by Licensee thereafter.

No adjustment shall be made under this Section 2 with respect to the issuance of shares (a) to employees, consultants, officers or directors of Licensee pursuant to any bona fide stock option plan of Licensee approved by the Board of Directors, (b) shares issued upon any stock split or stock dividend, (c) shares issued for fair value (as determined in good faith by the Board of Directors) pursuant to the acquisition of any other company by Licensee by merger or purchase of substantially all of the assets or other reorganization.

## 2.2 Closing Deliveries

On the Effective Date, in addition to the certificates evidencing the Shares, Licensee shall deliver to USFRF the following:

- 2.2.1 a certificate from Licensee, dated as of the Effective Date and signed by the Secretary or an Assistant Secretary of Licensee, certifying that the attached copies of the Certificate of Incorporation, Bylaws of Licensee, and resolutions of the Board of Directors of Licensee approving the License Agreements, this Agreement and the transactions contemplated thereby, are all true, complete and correct and that such resolutions remain unamended and in full force and effect.

## **Section 3** **Representations and Warranties**

### 3.1 Representations and Warranties by Licensee

Licensee represents and warrants to USFRF that:

- 3.1.1 Licensee is a duly organized and validly existing corporation under the laws of the State of Delaware with adequate power and authority to conduct the business in which it is now engaged or currently proposed to be engaged, and Licensee is duly qualified to do business as a foreign corporation and is in good standing in such other states or jurisdictions as is necessary to enable it to carry on its business or own its properties.
- 3.1.2 There are no actions, suits, or proceedings pending or threatened against or affecting Licensee, its officers or directors in their capacity as such, its properties, or its patents in any court or before any governmental or administrative agency, which can have any material adverse effect on the business as now conducted or as currently proposed to be conducted, on the properties, the financial condition, or income of Licensee, or the transactions contemplated by this Agreement or the License Agreements and Licensee is not in default under any order or judgment of any court or governmental or administrative agency.
- 3.1.3 Licensee is not a party to any agreement or instrument, or subject to any charter, bylaw, or other corporate restrictions materially adversely affecting its business and operations, present or prospective, or its property, assets, or condition, financial or otherwise.

- 3.1.4 Licensee is not in default or breach in the performance, observance, or fulfillment of any of the obligations, covenants, or conditions contained in any bond, debenture, note, or other evidence of indebtedness or any contract or other agreement of Licensee.
- 3.1.5 This Agreement has been duly authorized, executed, and delivered on behalf of Licensee and constitutes the valid and binding agreement of Licensee, enforceable in accordance with its terms, and Licensee has full power and lawful authority to issue, sell, and repurchase the Shares on the terms and conditions herein set forth.
- 3.1.6 Consummation of the transactions contemplated by this Agreement in compliance with provisions of this Agreement will not result in any breach of any of the terms, conditions, or provisions of, or constitute a default under, or result in the creation of any lien, charge, or encumbrance on, any property or assets of Licensee pursuant to any indenture, mortgage, deed of trust, agreement, corporate charter, bylaws, contract, or other instrument to which Licensee is a party or by which Licensee may be bound or any law, rule, regulation, qualification, license, order or judgment applicable to Licensee or any of its property.
- 3.1.7 Licensee is in compliance with all federal, state and local environmental laws and there are no conditions currently existing or contemplated which are likely to subject Licensee to damages, penalties, injunctive relief, removal costs, remedial costs or cleanup costs under any such laws or assertions thereof.
- 3.1.8 Attached hereto as Exhibit B and hereby made a part hereof are the Articles of Incorporation (including any amendments thereto) Bylaws (including any amendments thereto) of Licensee in effect on the date hereof.
- 3.1.9 Pursuant to its Articles of Incorporation, Licensee is authorized to issue 310,000,000 Shares (300,000,000 shares of common stock and 10,000,000 shares of preferred stock), of which 49,278,701 Shares are issued and outstanding. All issued and outstanding Shares are, and the Shares issuable to USFRF will be, validly issued, fully paid and nonassessable, and are not subject to any preemptive rights. There are no other authorized or outstanding Equity Securities of any class, kind, or character, and there are no outstanding subscriptions, options, warrants, or other agreements, or commitments obligating Licensee to issue any additional shares of its capital stock of any class, or any options or rights with respect thereto, or any securities convertible into any shares of stock of any class. No person has any preemptive rights, rights of first refusal, "tag along" rights, rights of co-sale or any similar rights with respect to the issuance of the Shares contemplated hereby. **NOTE: This Section 3.1.9 shall be completed based upon information provided by Licensee on or before July 31, 2018.**
- 3.1.10 Attached hereto as Exhibit C and hereby made a part hereof is a list of all restrictions on the transfer of any Shares or other securities of Licensee and all agreements between any shareholders or convertible debt holders of Licensee regarding the valuation, voting or transfer of any Shares or other securities of Licensee.
- 3.1.11 Attached hereto as Exhibit D and hereby made a part hereof are the unaudited Financial Statements of Licensee for the year ended April 30, 2018. These financial statements are true and complete and are in accordance with the books and records of Licensee. As of the date of the most recent financial statements provided to USFRF under this Agreement, Licensee has no material liabilities, absolute or contingent, that are not reflected in such financial statements except obligations incurred in the ordinary course of business and the License Agreements. **NOTE: This Exhibit D shall be provided by Licensee on or before August 31, 2018.**

- 3.1.12 Since the date of the most recent financial statements provided to USFRF under this Agreement, there has been no: (a) material adverse change in the condition, financial or otherwise, of Licensee other than changes in the ordinary course of business; (b) damage or loss, whether or not covered by insurance, materially and adversely affecting Licensee's properties or business taken as a whole; and (c) declaration or setting aside, or payment of any dividend or other distribution in respect of the stock of Licensee or any direct or indirect redemption, purchase or other acquisition of such shares.
- 3.1.13 Licensee has timely filed all tax returns and reports required to be filed by it. Licensee has timely paid all taxes, interest and penalties required to be paid pursuant to said returns or otherwise required to be paid by it.
- 3.1.14 Attached hereto as Exhibit E is a true and complete record of (i) issued and outstanding Shares as of the Effective Date and the holders thereof, and (ii) Shares issuable under options, warrants or other convertible equity or debt instruments outstanding as of the Effective Date, whether vested or non-vested, restricted or unrestricted, the holders thereof, the exercise price or conversion price thereof and an outline of all other material terms with respect thereto.

3.2 Representations and Warranties by USFRF

USFRF represents and warrants to Licensee that:

- 3.2.1 USFRF is acquiring the Shares for investment for its own account and not with a view to resale or distribution within the meaning of the Securities Act, and USFRF does not intend to divide its participation with other or to resell or otherwise dispose of all or any part of the Shares without registration under the Securities Act, except to Licensee or unless and until it determines at some future date that changed circumstances, not now in its contemplation, make such disposition advisable.
- 3.2.2 This Agreement has been duly authorized, executed, and delivered on behalf of USFRF and constitutes the valid and binding agreement of USFRF, enforceable in accordance with its terms, and USFRF has full power and lawful authority to acquire the Shares on the terms and conditions herein set forth.

3.3 Survival and Timing of Warranties

The warranties and representation made in this Section 3 shall survive the closing of any issuance of shares to USFRF. The warranties and representations made in this Section 3 shall be true and correct as of the date of this Agreement and as of the date the Shares are issued to USFRF.

**Section 4** Miscellaneous Covenants

4.1 Financial Statements and Other Information

As long as USFRF owns any Equity Securities, Licensee shall promptly provide to USFRF such Financial Agreements, amendments to or restatements of its Articles of Incorporation or Bylaws, stock transfer restrictions and agreements among shareholders with respect to the valuation, transfer or voting of Shares and amendments thereto as may be effected from time to time, and such other information respecting the business, affairs, and financial condition of Licensee as USFRF may reasonably request. Financial Statements shall be provided within the time that such Financial Statements are required to be provided to holders of preferred stock of Licensee. USFRF's representatives may visit and inspect any of the properties, books and information of Licensee, upon reasonable notice, during business hours and in a manner not disruptive to the business of the Licensee.

#### 4.2 Preemptive Rights

- 4.2.1 In addition to its other rights under this Agreement, USFRF shall have a preemptive right to acquire such Shares or other Equity Securities that may be issued from time to time by Licensee while USFRF remains the owner of any Equity Securities. Such preemptive right shall apply with respect to all Equity Securities issued by Licensee after the Effective Date, whether such additional Equity Securities constitute a part of the Equity Securities presently or subsequently authorized or constitute Equity Securities held in the treasury of Licensee, and regardless of whether such Equity Securities are to be issued for cash, property (other than cash) or services. Such preemptive right shall not apply to (i) Equity Securities issued pursuant to the acquisition of another corporation or business entity by Licensee or one or more of its wholly owned subsidiaries by merger, consolidation, share exchange, purchase of substantially all the assets or other reorganization whereby the shareholders of Licensee immediately prior to the transaction owns in the aggregate more than 50% of the voting power of Licensee or other surviving entity after the transaction; (ii) Equity Securities issued to employees, consultants or directors of Licensee pursuant to any incentive agreement or arrangement approved by the Board of Directors of Licensee; (iii) Equity securities issued pursuant to any stock dividend, stock split, combination or other reclassification by Licensee of any of its capital stock; or (iv) Equity Securities issued in connection with real or personal property leases or loans or lines of credit from financial institutions.
- 4.2.2 In furtherance of the preemptive rights hereby granted USFRF, Licensee agrees to provide USFRF with not less than fifteen (15) days prior written notice (an "Equity Security Issuance Notice") of its intent to issue any Equity Securities. Such notice should specify in reasonable detail the Equity Securities to be issued, including class, total number of shares and the applicable rights and preferences associated therewith, including, if applicable, conversion rights into Shares, and the purchase price for the Equity Securities USFRF may purchase pursuant to its preemptive rights hereby granted. USFRF shall have the right to acquire Equity Securities of the type being issued in an amount equal to USFRF's Proportionate Share Percentage of the aggregate Equity Securities of that type that are to be issued to all persons or entities pursuant to that issuance. The terms and conditions of USFRF's exercise of its preemptive rights, including the consideration to be paid for such Equity Securities, shall be no less favorable to USFRF than the most favorable price, terms and conditions offered to any other shareholder or prospective shareholder with respect to the Equity Securities then being issued.
- 4.2.3 In order to exercise USFRF's preemptive rights, USFRF shall deliver written notice thereof to Licensee within fifteen (15) days following its receipt of the Equity Securities Issuance Notice to which such exercise relates, accompanied by full payment of the purchase price for the Equity Securities to be purchased by USFRF in connection with the exercise of such preemptive rights. USFRF may, at its option, exercise such preemptive rights to some or all of the Equity Securities to which it has preemptive rights under this Section 4.2. In the event that any Equity Securities are to be issued by Licensee in return for property (other than cash) or services, in calculating the purchase price of the Equity Securities with respect to which USFRF has preemptive rights pursuant to this Section 4.2, the purchase price for the Equity Securities to be issued in exchange for non-cash property or services shall be equal to the fair market value of such property or services as determined in good faith by the Board of Directors of Licensee.

4.3 Issuance of Shares/Options to Affiliates/Founders

Licensee shall not issue any Equity Securities (including Shares) to any of the shareholders of Licensee listed on Exhibit A attached hereto (the "Founders"), Affiliate thereof or Affiliate of Licensee for less than the fair market value of that security. Licensee shall have the burden of proving that the consideration to be paid for any such Equity Securities equals the fair market value of such Equity Securities issued.

4.4 Piggyback Registration Rights

- 4.4.1 At any time after the first anniversary of the date that a registration statement covering an initial public offering of Shares of Licensee becomes effective, as soon as practicable after a written request from USFRF to effect a registration with respect to all or part of the Shares owned by USFRF, Licensee will use its diligent best efforts to effect such Registration, cause it to become effective promptly and maintain it as effective for at least 36 months (or less if all the Shares included therein are sooner sold). If so requested by USFRF, Licensee shall enter into an underwriting agreement in customary form with any underwriter selected by USFRF with respect to such Registration.
- 4.4.2 If the Licensee proposes to register any of its securities either for its own account or the account of a security holder or holders, other than a registration on any form which does not permit secondary sales, Licensee will promptly give USFRF written notice thereof and include in such Registration (and any related qualification under Blue Sky laws or other applicable laws), and in any underwriting involved therewith, all of the Shares specified in a written request made by USFRF within twenty (20) days after Licensee's written notice to USFRF.
- 4.4.3 All expenses incurred by Licensee and USFRF in connection with any Registration hereunder, including reasonable fees and disbursements of accountants and counsel for USFRF, but excluding underwriting discounts and commissions and transfer taxes, shall be borne solely by Licensee.
- 4.4.4 To the extent permitted by law, Licensee will indemnify USFRF and each of its officers, directors, and control persons ("USFRF indemnified parties") against all claims, losses, damages and liabilities ("Claims") arising out of or on any untrue statement (or alleged untrue statement) of a material fact contained in any prospectus or other document incident to any such Registration, or any omission (or alleged omission) to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading (to the extent not made in reliance upon written information furnished by USFRF specifically for use in such Registration) or any violation by Licensee of the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, and will reimburse each USFRF indemnified party for any legal and other expenses reasonably incurred in connection with investigating and defending or settling any such Claim.

#### 4.5 Rule 144 Reporting

With a view to making available to USFRF the benefits of certain rules and regulations of the Commission which may permit USFRF to sell securities of Licensee to the public without registration, Licensee agrees to:

- 4.5.1 Make and keep public information available, as those terms are understood and defined in Rule 144 under the Securities Act, at all times following the effective date of the first registration under the Securities Act filed by Licensee for an offering of its securities to the general public;
- 4.5.2 Use its best efforts to file with the Commission in a timely manner all reports and other documents required of Licensee under the Securities Act and the Exchange Act at any time following registration of any of its securities under the Securities Act or Exchange Act; and
- 4.5.3 So long as USFRF owns any Shares, furnish to USFRF forthwith upon request a written statement by Licensee as to its compliance with the reporting requirements of Rule 144 (at any time following the effective date of the first registration statement filed by Licensee for an offering of its securities to the general public), and of the Securities Act and the Exchange Act following registration of any of its securities under the Securities Act or Exchange Act, a copy of the most recent annual or quarterly report of Licensee, and such other reports and documents so filed as USFRF may reasonably request in availing itself of any rule or regulation of the Commission allowing USFRF to sell any such securities without registration.

#### 4.6 Transfer or Assignment of Registration Rights

The rights to cause Licensee to register the securities granted to USFRF hereunder may be transferred or assigned by USFRF to a transferee or assignee of any of USFRF's Shares; *provided, however*, that such transfer or assignment of Shares was permitted under this Agreement.

### **Section 5** Tag-Along Rights

- 5.1 If, at any time, prior to an initial public offering, any of the shareholders set forth on Exhibit E (the "Disposing Shareholders") propose to sell, within a two-year period and in any one or more private transactions, capital stock of Licensee which, in the aggregate, represents more than fifty percent (50%) of the outstanding capital stock of Licensee on a fully-diluted basis to any one or more third parties (a "Third Party"), then USFRF shall have the right to participate (a "Tag-along Right") in such sale with respect to the Shares, on a pro rata basis for the same consideration per share and otherwise on the same terms as the Disposing Shareholders. If circumstances occur which give rise to the Tag-along Right, then the Disposing Shareholders shall give written notice to USFRF, providing the particulars of the proposed sale to the Third Party and advising USFRF of its Tag-along Rights. USFRF may exercise its Tag-along Right by written notice to the Company and the Disposing Shareholders within twenty-five (25) days of the date of mailing of the Disposing Shareholders' notice stating the number of shares that USFRF wishes to sell, up to the maximum permitted herein. If USFRF gives written notice indicating that it wishes to sell, USFRF shall be obligated to sell that number of Shares specified in its written acceptance notice upon the same terms and conditions as the Disposing Shareholders are selling to the Third Party and shall not be subject to the requirements of Section 7. For purposes of this Section 5, "pro rata" means the percentage derived by dividing the aggregate Shares then owned by USFRF by the aggregate Shares then owned by USFRF and the Disposing Shareholders. The Company agrees to cause its shareholders, including those persons who become shareholders from time to time in the future, to enter into an agreement to carry out the provisions of this Section 5.1.

- 5.2 Upon receipt of such notice, Licensee shall tender the specified number of Shares, if any, at the same price applicable to the Transferring Shareholders in the transaction. In each case, tender shall be made upon the same terms and conditions applicable to the Transferring Shareholders in the transaction or, in the discretion of the acquirer or successor to Licensee, upon payment of the purchase price to the Shareholder in immediately available funds.

**Section 6** **Termination**

- 6.1 Unless terminated sooner by either party as provided below, this Agreement shall terminate on the date that USFRF, after having been issued Shares hereunder, no longer owns any Equity Securities. If this Agreement terminates automatically as provided in this Section 6, the License Agreements shall remain in effect according to the terms specified therein.
- 6.2 If Licensee at any time fails to timely issue Shares to USFRF on a timely basis, or otherwise commits a material breach of this Agreement, or if any of the representations or warranties made by Licensee are untrue in any material respect as of any date on which they are required to be true and correct, and Licensee fails to remedy any such breach or default within thirty (30) days after written notice thereof by USFRF, USFRF may, at its option, terminate either this Agreement, the License Agreements, or all of them.

**Section 7** **Assignability**

Except as set forth in Section 4.6, neither party may assign its rights or obligations under this Agreement, except that Licensee may assign this Agreement in connection with the sale of all or substantially all of the assets or stock of the Licensee, whether by merger, acquisition or otherwise, if the successor assumes all of the Licensee's obligations hereunder.

**Section 8** **Miscellaneous**

This Agreement shall be construed exclusively in accordance with the internal laws of the State of Florida.

**Section 9** **Notices**

Any notice required to be given pursuant to the provisions of this Agreement shall be in writing and shall be deemed to have been given at the earlier of the time when actually received as a consequence of any effective method of delivery, including but not limited to hand delivery, transmission by telecopier, or delivery by a professional courier service or the time when sent by certified or registered mail addressed to the party for whom intended at the address below or at such changed address as the party shall have specified by written notice, provided that any notice of change of address shall be effective only upon actual receipt:

to Licensor:

USF Division of Patents & Licensing  
Attn: Assistant Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, FL 33612

with a copy to:

USF Division of Patents & Licensing  
Attn: Assistant Vice President  
3802 Spectrum Blvd, Suite 100  
Tampa, FL 33612

to Licensee:

Alzamend Neuro, Inc.  
Attn: CEO  
50 W Broadway, Suite #300  
Salt Lake City, UT 84101

**Section 10**     **Integration**

This Agreement constitutes the full understanding between the parties with reference to the subject matter hereof, and no statements or agreements by or between the parties, whether orally or in writing, except as provided for elsewhere in this 10, made prior to or at the signing with respect to the subject matter hereof, shall vary or modify the written terms of this Agreement. Neither party shall claim any amendment, modification, or release from any provisions of this Agreement by mutual agreement, acknowledgment or otherwise, unless such mutual agreement is in writing, signed by the other party, and specifically states that it is an amendment to this Agreement.



IN WITNESS WHEREOF, the parties hereto have duly executed this Agreement on the dates indicated below.

**THE UNIVERSITY OF SOUTH FLORIDA RESEARCH FOUNDATION, INC.**

\_\_\_\_\_, Date: \_\_\_\_\_, 2018

Valerie Landrio McDevitt, Associate Vice President  
Technology Transfer Office

**ALZAMEND NEURO, INC.**

\_\_\_\_\_, Date: July 18, 2018

Philip E. Mansour, President and CEO

Reviewed by Licensor's Attorney:

\_\_\_\_\_  
(name typed)  
(Attorney shall not be deemed a signatory to this Agreement.)

**Exhibit A - Definitions In Equity Agreement**

- (1) "Shares" shall mean shares of Licensee's common stock, \$.0001 par value per share. **Note: This portion of Exhibit A to be provided by Licensee on or before July 31, 2018**
- (2) "License Agreements" shall mean the LIC18111 license agreements entered into between USFRF and Licensee of even date herewith pertaining to each Licensed Patent Group, as such term is defined in each License Agreement.
- (3) "Affiliate" shall mean any person who is related by blood or marriage to any person or entity who owns more than twenty percent of the issued and outstanding shares of Licensee or to any officer, director, or employee of Licensee or any entity in which any such person has a direct or indirect beneficial ownership interest or for which any such person serves as a director, officer or employee.
- (4) "Financial Statements" shall mean a balance sheet, and the related statements of earnings, stockholders' equity and cash flow as of the end of the last fiscal year that has been completed when the statements are to be provided to USFRF and a balance sheet and income statement as of the end of the last fiscal quarter, which financial statements shall be in the form and delivered at the time that such financial statements are delivered to holders of preferred stock of Licensee. Financial Statements shall be true and complete and prepared in accordance with the books and records of Licensee and with generally accepted accounting principles.
- (5) "Equity Securities" shall mean the Shares, any other capital stock of Licensee (including preferred shares), and any securities of Licensee that are convertible into capital stock of Licensee or that carry a right to subscribe to or acquire capital stock of Licensee.
- (6) "Register," "Registered," and "Registration" shall refer to a registration effected by preparing a filing a Registration Statement in compliance with the Securities Act, and the declaration or ordering of the effectiveness of such Registration Statement.
- (7) "Proportionate Share Percentage" with respect to USFRF, for purposes of Section 4.2, shall mean the percentage derived by dividing the aggregate Shares then owned by USFRF by the total number of issued and outstanding Shares on an as-converted basis at such time.
- (8) "Securities Act" shall mean the Securities Act of 1933, as amended, or any similar federal statute, and the rules and regulations of the Securities and Exchange Commission issued under such act, as they each may, from time to time, be in effect.
- (9) "Commission" shall mean the Securities and Exchange Commission or any other federal agency at the time administering the Securities Act.
- (10) "Exchange Act" shall mean the Securities Exchange Act of 1934, as amended.

**Exhibit B - Articles of Incorporation and Bylaws**

**Bylaws to be provided by Licensee on or before July 31, 2018**

# Delaware

The First State

Page 1

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF  
DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT  
COPY OF THE CERTIFICATE OF INCORPORATION OF "ALZAMEND NEURO,  
INC.", FILED IN THIS OFFICE ON THE TWENTY-SIXTH DAY OF  
FEBRUARY, A.D. 2016, AT 3:05 O'CLOCK P.M.

A FILED COPY OF THIS CERTIFICATE HAS BEEN FORWARDED TO THE  
NEW CASTLE COUNTY RECORDER OF DEEDS.



5976073 8100  
SR# 20161234328

You may verify this certificate online at [corp.delaware.gov/authver.shtml](http://corp.delaware.gov/authver.shtml)

A handwritten signature in black ink, appearing to read "JBULLOCK", written over a horizontal line.

Authentication: 201900010  
Date: 02-29-16

CERTIFICATE OF INCORPORATION

OF

ALZAMEND NEURO, INC.

State of Delaware  
Secretary of State  
Division of Corporations  
Delivered: 4/3/16 PM 02:26 2016  
FILED: 4/3/16 PM 02:26 2016  
SR 20161234328 - File Number 8976873

FIRST: The name of the Corporation is Alzamend Neuro, Inc. (the "Corporation").

SECOND: The address of the registered office of the Corporation in the State of Delaware is 2711 Centerville Road, Suite 400, Wilmington, DE 19808, New Castle County. The name of its registered agent at that address is Corporation Service Company.

THIRD: The purpose of the Corporation is to engage in any lawful act or activity for which a corporation may be organized under the General Corporation Law of the State of Delaware as set forth in Title 8 of the Delaware Code (the "DGCL").

FOURTH: The Corporation is authorized to issue two classes of stock to be designated, respectively, "Common Stock" and "Preferred Stock." The total number of shares which the Corporation is authorized to issue is 160,000,000 shares. 150,000,000 shares shall be Common Stock, each having a par value of \$0.0001. 10,000,000 shares shall be Preferred Stock, each having a par value of \$0.0001.

The Preferred Stock may be issued from time to time in one or more series. The Board of Directors is hereby expressly authorized to provide for the issue of all or any of the shares of the Preferred Stock in one or more series, and to fix the number of shares and to determine or alter for each such series, such voting powers, full or limited, or no voting powers, and such designation, preferences, and relative, participating, optional, or other rights and such qualifications, limitations, or restrictions thereof, as shall be stated and expressed in the resolution or resolutions adopted by the Board of Directors providing for the issuance of such shares and as may be permitted by the DGCL. The Board of Directors is also expressly authorized to increase or decrease the number of shares of any series subsequent to the issuance of shares of that series, but not below the number of shares of such series then outstanding. In case the number of shares of any series shall be decreased in accordance with the foregoing sentence, the shares constituting such decrease shall resume the status that they had prior to the adoption of the resolution originally fixing the number of shares of such series.

FIFTH: The name and mailing address of the Sole Incorporator is as follows:

<u>Name</u>	<u>Address</u>
<u>Milton C. Auli, III</u>	<u>P.O. Box 3587</u> <u>Tustin, CA 92781</u>

SIXTH: The following provisions are inserted for the management of the business and the conduct of the affairs of the Corporation, and for further definition, limitation and regulation of the powers of the Corporation and of its directors and stockholders:

(1) The business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors.

(2) The directors shall have concurrent power with the stockholders to make, alter, amend, change, add to or repeal the Bylaws of the Corporation.

(3) The number of directors of the Corporation shall be as from time to time fixed by, or in the manner provided in, the Bylaws of the Corporation. Election of directors need not be by written ballot unless the Bylaws so provide.

(4 ) No director shall be personally liable to the Corporation or any of its stockholders for monetary damages for breach of fiduciary duty as a director, except for liability (i) for any breach of the director's duty of loyalty to the Corporation or its stockholders, (ii) for acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law, (iii) pursuant to Section 174 of the DGCL or (iv) for any transaction from which the director derived an improper personal benefit. Any repeal or modification of this Article SIXTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of such repeal or modification with respect to acts or omissions occurring prior to such repeal or modification.

(5) In addition to the powers and authority hereinbefore or by statute expressly conferred upon them, the directors are hereby empowered to exercise all such powers and do all such acts and things as may be exercised or done by the Corporation, subject, nevertheless, to the provisions of the DGCL, this Certificate of Incorporation, and any Bylaws adopted by the stockholders; provided, however, that no Bylaws hereafter adopted by the stockholders shall invalidate any prior act of the directors which would have been valid if such Bylaws had not been adopted.

SEVENTH: Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws may provide. The books of the Corporation may be kept (subject to any provision contained in the DGCL) outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

EIGHTH: The Corporation reserves the right to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, in the manner now or hereafter prescribed by statute, and all rights conferred upon stockholders herein are granted subject to this reservation.

\* \* \* \* \*

I, THE UNDERSIGNED, being the Sole Incorporator hereinbefore named, for the purpose of forming a corporation pursuant to the DGCL, do make this Certificate, hereby declaring and certifying that this is my act and deed and the facts herein stated are true, and accordingly have hereunto set my hand this 25th day of February, 2016.



by \_\_\_\_\_

Milton C. Ault, III  
Sole Incorporator

**Exhibit C - Stock Restrictions**

(1) Restrictive Legend.

Each certificate representing (i) the Shares and (ii) any other securities issued in respect of the Shares upon any stock split, stock dividend, recapitalization, merger, consolidation or similar event, shall (unless otherwise permitted by the provisions of Section (2) below) be stamped or otherwise imprinted with a legend in substantially the following form (in addition to any legend required under applicable state securities laws).

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED, OR APPLICABLE STATE SECURITIES LAWS. THESE SECURITIES HAVE BEEN ACQUIRED FOR INVESTMENT AND NOT WITH A VIEW TO DISTRIBUTION OR RESALE, AND MAY NOT BE SOLD, MORTGAGED, PLEDGED, HYPOTHECATED OR OTHERWISE TRANSFERRED WITHOUT AN EFFECTIVE REGISTRATION STATEMENT FOR SUCH SECURITIES UNDER THE SECURITIES ACT OF 1933, AS AMENDED, AND ANY APPLICABLE STATE SECURITIES LAWS, OR THE AVAILABILITY OF AN EXEMPTION FROM THE REGISTRATION PROVISIONS OF THE SECURITIES ACT OF 1933, AS AMENDED, AND APPLICABLE STATE SECURITIES LAWS.

Each holder consents to Licensee's making a notation on its records and giving instructions to any transfer agent of the Shares in order to implement the restrictions on transfer established in this Section (1). Such legend shall be removed by Licensee from any certificate at such time as the holder of the Shares represented by the certificate satisfies the requirements of Rule 144(k) under the Securities Act, provided that Rule 144(k) as then in effect does not differ substantially from Rule 144(k) as in effect as of the date of this Agreement and other applicable regulations do not then require such legend to be included on the Shares, and provided further that Licensee has received from the holder a written representation that (i) such holder is not an Affiliate of Licensee and has not been an Affiliate during the preceding three months, (ii) such holder has beneficially owned the Shares represented by the certificate for a period of at least two years, (iii) such holder otherwise satisfies the requirements of Rule 144(k) as then in effect with respect to such Shares, and (iv) such holder will submit the certificate for any such Shares to Licensee for reapplication of the legend at such time as the holder becomes an Affiliate of Licensee or otherwise ceases to satisfy the requirements of Rule 144(k) as then in effect.

(2) Notice of Proposed Transfers.

The holder of each certificate representing Shares by acceptance thereof agrees to comply in all respects with the provisions of this Section (2). Prior to any proposed sale, assignment, transfer or pledge of Shares, unless there is in effect a registration statement under the Securities Act covering the proposed transfer, the holder thereof shall give written notice to the Licensee of such holder's intention to effect such transfer, sale, assignment or pledge in sufficient detail, and shall be accompanied at such holder's expense by a written opinion of legal counsel who shall, and whose legal opinion shall, be reasonably satisfactory to the Licensee addressed to the Licensee, to the effect that the proposed transfer of the Shares may be effected without registration under the Securities Act. Each certificate evidencing the Shares transferred as above provided shall bear, except if such transfer is made pursuant to Rule 144, the appropriate restrictive legend set forth in Section (1) above, except that such certificate shall not bear such restrictive legend if in the opinion of counsel for such holder and Licensee such legend is not required in order to establish compliance with any provisions of the Securities Act. Prior to any transfer of the Shares in accordance with this Section (2), such transferee shall execute and deliver a form of agreement reasonably acceptable to the Licensee wherein the transferee agrees to be bound by the provisions of this Exhibit C.



(3) Transfer to Competitor.

No holder shall transfer any Shares to a competitor of Licensee, as determined by the Board of Directors of Licensee in good faith. This provision shall terminate after the closing of the sale of Equity Securities of Licensee registers pursuant to a registration statement filed under the Securities Act.

**Exhibit D - Financial Statements**

*To be provided by Licensee on or before August 31, 2018*

**Exhibit E - List of Stockholders and Option Holders**

*To be provided by Licensee on or before July 31, 2018*

**Exhibit F - Form of Opinion**

*To be provided by Licensee on or before July 31, 2018*